University of Alberta

Access to Essential Medicines: Analysis of the TRIPs Amendment and Canada's *Jean Chrétien Pledge to Africa* Act

by

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ABSTRACT

Pharmaceutical innovations in Europe and North America have led to the production of medicines which could significantly reduce the incidences and prevalence of diseases such as AIDS, malaria and tuberculosis and alleviate the sufferings of the infected. However, people sufferring these diseases can hardly access these drugs, owing primarily to their exorbitant prices. This thesis, which recognizes global efforts at promoting access to essential medicines via the *Trade Related Aspects of Intellectual Property Rights* (TRIPs) of 1995 and the 2003 amendment to its Article 31, argues that the access to drugs mechanisms of western countries which possess the capacity to produce drugs are quite onerous to utilise in manufacturing generic drugs. I have thus designed a scheme, modeled on and targeted at harnessing the benefits of the Regional Trade Agreement (RTA) system, which will enable economically disadvantaged countries to easily purchase much needed essential drugs.

To

Samuel Otokhile & Oloaigbe Ohioze, for my conception

…John Odion Ohioze, who nurtured me despite the challenges

And especially to the *I am that I am*,

for His graces and mercies.

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LIST OF ABBREVIATIONS

AIDS	-	Acquired Immune Deficiency Syndrome
ARV	-	Antiretroviral
AZT	-	Azidothymidine
CAMR	-	Canada's Access to Medicines Regime
CDC	-	Centers for Disease Control
CGPA	-	Canadian Generic Pharmaceutical Association
FTA	-	Free Trade Agreement
GSK	-	GlaxoSmithKline
HAART	-	Highly Active Antiretroviral Therapy
HIV	-	Human Immunodeficiency Virus
IFPMA	-	International Federation of Pharmaceutical Manufacturers and Associations
IIPI	-	International Intellectual Property Institute
JCPA	-	Jean Chrétien Pledge to Africa Act
LDC	-	Least-developed Country
MIPF	-	Medical Innovation Prize Fund
NAP	-	National AIDS Programme
NGO	-	Non-governmental Organisation
NIH	-	National Institute for Health
OECD	-	Organisation for Economic Cooperation and Development
PhRMA	-	Pharmaceutical Research and Manufacturers of America

R&D	-	Research and Development
SACU	-	South African Custom Union
SPC	-	Supplementary Protection Certificate
STD	-	Sexually Transmitted Disease
TAC	-	Treatment Action Campaign
TRIPs	-	Trade Related Aspects of Intellectual Property Rights
UNAIDS	-	Joint United Nations Programme on HIV/AIDS
WHO	-	World Health Organization
WIPO	-	World Intellectual Property Organisation
US-CAFTA	-	US-Central American Free Trade Agreement

> In June 1981 we saw a young gay man with the most devastating immune deficiency we had ever seen. We said, 'we don't know what this is, but we hope we don't ever see another case like this again.'[1]

INTRODUCTION

In December 2003, the World Health Organization ("WHO") in concert with the Joint United Nations Programme on HIV/AIDS ("UNAIDS") launched the "3 by 5" programme[2]; a global initiative to scale up access to antiretroviral ("ARV") therapy[3] for three million sufferers of Acquired Immune Deficiency Syndrome ("AIDS") in developing countries by 2005.[4]

This initiative represented a wake up call to the world that though prevention is desirable, treatment for those infected with the disease is equally an important goal. Following the elapsing of its "3 by 5" scheme, UNAIDS has again renewed its commitment to the singular, yet daunting task of making ARV therapy easily affordable to the teeming AIDS afflicted population in developing countries.

In June 2006, the United Nations General Assembly High-Level Meeting on AIDS agreed to work towards the broad goal of "universal access to comprehensive

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[1] The Joint United Nations Programme on HIV/AIDS, *2006 Global AIDS Epidemic Report: Introduction,* Online: UNAIDS http://data.unaids.org/pub/GlobalReport/2006/2006_GR_CH01_en.pdf (accessed 5 February 2007)

[2] By the "3 by 5" programme, the WHO and UNAIDS planned to provide three million people living with HIV/AIDS in low and middle-income countries with life-prolonging antiretroviral treatment (ART) by the end of 2005. The WHO describes it as a step towards the goal of making universal access of HIV/AIDS prevention and treatment accessible for all who need them as a human right. See WHO, "The 3 by 5 Initiative" Online: WHO, <http://www.who.int/3by5/en/>

[3] This is the main type of treatment for AIDS. It does not cure AIDS but sustains the lives of those infected by preventing a replication of the virus. See Avert, *Introduction to HIV/AIDS Treatment*, online: <http://www.avert.org/introtrt.htm> (accessed 26 January 2007)

[4] World Health Organization, *Treating 3 million by 2005: Making it happen, the WHO strategy.* Online: WHO http://www.who.int/3by5/publications/documents/en/3by5StrategyMakingItHappen.pdf (Accessed 26 January 2007).

prevention programmes, treatment, care and support" by 2010.[5] This new initiative on equality of access to AIDS prevention, medication and care replaced the "3 by 5" programme. One can safely state that there is no shortage of policies and legislative instruments relevant to the delivery of treatment essentials like ARVs, care and support to the afflicted. In fact, the WHO had identified a total of two hundred and ninety three (293) national and international legislations, regulations, resolutions and policies dealing with the control of AIDS and Human Immunodeficiency Virus ('HIV') infection, as far back as 1989.[6]

Perhaps the solution to the access to AIDS medicines dilemma is not in a plethora of laws. I argue that this access dilemma is presently bereft of solution(s) because of the disconnections between international and national access instruments. A proper connection, where one exists, between a global access instrument and its domestic replication by leading drug producing countries would not only ensure uniformity of rules and processes between the Trade Related Aspects of Intellectual Property Rights (TRIPs)[7] and national regimes but also of end results. Users of the access instrument would find it easier to navigate the process of accessing cheap drugs if countries with the capacity to produce drugs operate similar access rules as the international instrument. I shall demonstrate this assertion by undertaking legal and policy analysis of the recent amendment to the TRIPs, which is an international

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[5] World Health Organisation, *Towards Universal Access by 2010- WHO Advocacy Report*, online: WHO <http://www.who.int/hiv/toronto2006/towardsuniversalaccess.pdf>

[6] World Health Organisation, *Legislative Responses to AIDS* (The Netherlands, Martinus Nijhoff, 1989).

[7] WTO, *Agreement on Trade-Related Aspects of Intellectual Property Rights*, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organisation, Annex 1C, LEGAL INSTRUMENTS- RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) Online: WTO <http://www.wto.org/english/docs_e/legal_e/27_trips_01_e.htm >

agreement reached by members of the World Trade Organisation ('WTO')[8]. The TRIPs Amendment is intended to overcome the difficult issues in the access to drugs challenge. In order to expose the points of divergence between international and national access regimes, I shall also undertake an in-depth analysis of Canada's amendment of its *Patent Act* and the *Food and Drugs Act*[9], which was conceived as a response to the global clamour for access to drugs. The *Jean Chrétien Pledge to Africa Act* ('JCPA'), as Canada's amendment of its *Patent Act* and the *Food and Drugs Act* is commonly called, is the legal framework for Canada's Access to Medicines Regime ('CAMR').

Although both the TRIPs Amendment and the JCPA share similar access to medicines objectives, the latter appears restrictive in some important particulars. I propose an immediate amendment of the JCPA as necessary to bring it in line with the recent TRIPs Amendment, with particular emphasis on enlarging the list of pharmaceutical products exportable to developing and least developed countries and streamlining the conditions for the grant of compulsory licenses to generic companies. An amendment will not only allow for increase usage of the instrument, it will also help tackle the access to drugs issue.

My choice of the JCPA proceeds from the following reasons. One, it is the foremost and most detailed response to the call for flexibility in intellectual property protection for antiretrovirals in line with the amendment to TRIPS. Two, a number of

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[8] The WTO is the only international organisation dealing with the rules of trade between nations. It was established on 1 January 1995, after eight years of rounds of negotiations (the Uruguay Round Agreement of 1986-1994). See *WTO in Brief*, online: WTO <http://www.wto.org/english/thewto_e/whatis_e.htm >

[9] *Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa Act)*, R.S.C. 2004, c. C-23. ('JCPA').

countries are in the process of following Canada's lead by enacting similar or amending extant Patent legislation. Two of such countries, Norway and India, have already amended their Patent laws while the European Union adopted regulations to this effect in June 2006.[10] Three and most importantly, one can argue that the attainment of the objective of the TRIPs amendment and the promulgation of the JCPA – which is to facilitate access to cheap medicines for patients in poor countries- appears in doubt years after the introduction of these instruments.

In furtherance of this thesis, I therefore explore the disconnections between the TRIPs Amendment and the JCPA. Although, this paper does not pretend to proffer holistic solution(s) to the problem of access to antiretrovirals in poor countries[11], an alternative access model based on the principles of the Regional Trade Agreement (RTA) system is recommended for adoption in AIDS infected and poor regions of the world.

Structure of the Paper

This thesis is presented in five parts. Part I identifies as the most challenging social problem with HIV/AIDS, the need for access to essential medicines for the world's poor. It also presents the most recent data on the demographic spread of HIV/AIDS, focusing more on the economic disadvantaged continents of the world;

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[10] France, Switzerland and Korea are in the process of amending their Patent Laws for this purpose. See Ian F. Fergusson, *The WTO, Intellectual Property Rights, and the Access to Medicines Controversy*-Congressional Research Service (CRS) Report for the US Congress. December 12, 2006. Online: <http://www.fas.org/sgp/crs/misc/RL33750.pdf>.

[11] This classification is by the World Bank, which divides countries into low, lower middle, upper middle and high income classes based on their gross national income (GNI) per capita. See the World Bank, *Country Classification,* online: World Bank <http://www.worldbank.org/WBSITE/EXTERNAL/DATASTATISTICS> (accessed 5 February 2007).

and traces the international reactions to the AIDS scourge, beginning from the WHO's initial policy of prevention and control to the current policy of treatment (and in combination with prevention). This part also delves into the clinical justifications for recourse to the use of standard antiretroviral therapy instead of single or dual therapy in socially disadvantaged regions of the world.

Part II presents the two contending sides to the barrier to access controversy. Here, the barriers are compartmentalized into TRIPs-related and non-TRIPs related. Some of the most recent scholarly articles on the barrier to access debate are presented for an objective appreciation of the controversy.

The crux of my thesis is presented in Parts III and IV. In Part III, I examine the TRIPs Amendment- which came amidst the barriers to access debate- as a contemporary access to medicines mechanism which is designed to remedy the lacuna inherent in the TRIPs. Part IV critically analyses CAMR and reveals the level of its incoherence with the TRIPs Amendment. In Part V, I set out models variously articulated and put forward as solution(s) to the access to essential medicines problem in developing countries. Following from the identified shortcomings, I have devised a model which takes into cognizance the peculiarity of the socio-political and economic background of developing continents, particularly Africa.

PART I

IDENTIFYING THE PROBLEM

1.1 Introduction

One major issue that continues to generate public debate is access to AIDS treatment in poor, severely affected countries, in Africa, Asia and South America. Of these, sub-Saharan Africa has two-thirds of the world thirty three million, two hundred thousand persons living with AIDS[12], but possesses less than one percent of global financial resources. [13]

Recent statistics on the spread of AIDS put Africa, Asia and South America as the leading continents with most sufferers. According to UNAIDS *Global Summary of the AIDS Epidemic*[14] released in December 2007, sub-Saharan Africa recorded 22.5 million adults and children living with the disease. Asia recorded 4.8 million infected people. Latin America followed with 1.6 million AIDS sufferers. North America recorded 1.3 million AIDS cases while Europe produced just over 1.7 million people out of the 33.2 million worldwide.[15]

In 2007 alone, about 2.1 million people died of AIDS- related illnesses.[16] Of this figure, 1.6 million were recorded in sub-Saharan Africa. In this worst hit region, life expectancy at birth is now just 47 years, which is 30 years less than most high-

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[12] The Joint United Nations Programme on HIV/AIDS, *2007 AIDS Epidemic Update*, online: <http://data.unaids.org/pub/EPISlides/2007/2007_epiupdate_en.pdf>

[13] World Health Organisation, *Health Report 2006*, online: <http://bookorders.who.int/bookorders/anglais/detart1.jsp?sesslan=1&codcol=0206>

[14] *Supra* note 12.

[15] *Ibid.*

[16] *Ibid*

income countries.[17] The patients count from other equally poor countries in Latin America, Asia and the Caribbean is significantly different from those from sub-Saharan Africa, which suffers HIV/AIDS the most. Thus, AIDS is now effectively classified as a global epidemic and a public health scourge.[18]

This trend is not at all novel. In the second decade of the emergence of AIDS, the epidemic human form changed profoundly. Its demographic preponderance was no longer confined to western homosexual men but became largely a heterosexually transmitted disease in Asia, Latin America, the Caribbean, and particularly Africa.[19] By 2001, AIDS had become the leading cause of death in sub-Saharan Africa and the fourth largest cause of death worldwide.[20] These statistics, coupled with the fact that the disease has had a progressive growth in developing countries, leaves a question mark on the legal and policy responses by relevant international organisations to the disease in developing countries, since its discovery.

1.2 Initial Policy Response to AIDS

The WHO's initial policy response was through its *Social Aspects of AIDS Prevention and Control Programmes*.[21] Through this programme, the WHO emphasized the goals of prevention and control and sought to work with national authorities in developing over one hundred national programmes for the prevention

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[17] World Health Organisation, *Global AIDS Epidemic Continues to Grow,* online: WHO< http://www.who.int/hiv/mediacentre/news62/en/index.html> (accessed 5 February 2007)

[18] *Ibid.*

[19] Mr. Justice Edwin Cameron & Alok Gupta, *Global Access to Treatment: Achievements and Challenges* (2002) 7 Can. HIV/AIDS Pol'y & L. Rev. 1.

[20] *Ibid.*

[21] World Health Organisation, *Special Programme on AIDS*- WHO/SPA/GLO/87.2 of December 1, 1987.

and control of AIDS throughout the world.[22] This culminated in a glut of policies and legislations by many countries and federating states.[23] Prevention thus became the goal since a cure for the disease did not seem immediately foreseeable.[24]

In most countries the main prevention themes aimed at reducing sexual transmission of HIV by the use of condoms, having fewer number of partners, and preventing and treating sexually transmitted diseases ('STDs').[25] However, each of these approaches was more frequently used in industrialized than developing countries, with the exception of prevention and treatment of STDs, which received more emphasis in developing countries.[26] Abstinence, another theme of the prevention policy, is less fancied by experts who argued that it is yet to be proven to prevent the spread of AID.[27]

1.3 Basis for Policy Shift

Despite the initial focus on AIDS prevention strategies in most developing countries since the WHO's first policy response, the world has not witnessed a

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[22] *Supra*, note 6 at 273.

[23] For instance, China passed some regulations shortly after the WHO's initiative. See *Regulations on Surveillance and Control Measures Applicable to AIDS* (*Zhonghua Renmin Gongueguo Guowuyuan Gongbao*, 30 January 1988, No. 1, Serial No. 554, pp. 22-26). See also German Democratic Republic, *Fourth Regulations of 22 December 1987 for the Implementation of the Law on the Prevention and Control of communicable diseases in Humans- Compulsory notification in the case of AIDS (Gesetzblatt der Deutschen Demokratischen Republik,* Part I, 18 January 1988, No. 1, pp. 1-2*)*. Two states in the US also towed same line. See United States of America (North Carolina), *An Act to Provide for Instruction in the Public Schools on the Prevention of AIDS and other Communicable Disease.* Cap. 630, Laws 1987; United States of America (Rhode Island), *An Act Relating to Education in Prevention of AIDS*. Cap. 87-464 Public Law 1987.

[24] Daniel Carrasco, Melody Vander Straten & Stephen Tyring, *A Review of Antiretroviral Drugs* (2000) 13 Dermatologic Therapy 305 at 315.

[25] Jonathan Mann, *et al.*, eds., *AIDS in the World* (Bombay, Tata Institutes of Social Sciences, 1994) p. 33

[26] *Ibid.*

[27] Erika Check, *Criticism Swells Against AIDS Program's Abstinence Policy* (2007) 13:516 Nature Medicine

decline in the incidence of HIV in many developing countries. There was thus the need to shift to some other strategy like treatment. This was further buttressed by evidence from one developed and developing country whose strategy of treatment (or a combination of treatment and prevention) as opposed to prevention has caused a major decline in the incidences of AIDS. The situation in the US and Brazil may have presented a defining moment for focus on treatment initiative in the developing world.

In a recent study carried out in the US, it was observed that between 33, 480 and 41,784 AIDS deaths were either averted or delayed between 1995 and 2002 following a shift to treatment strategy as against 239,517 and 247,821 likely deaths that would have occurred without the advent of the treatment initiative in the US.[28] To further substantiate this fact, the US Centers for Disease Control ('CDC') and Prevention has equally recognised the positive impact of the treatment approach on AIDS in the US. According to CDC scientists, the advent of Highly Active Antiretroviral Therapy ('HAART')- but not behavioural change- was primarily responsible for the decline in AIDS deaths in the US.[29]

One major consensus reached at the 13th International AIDS conference in Durban, South Africa was that a strategic approach to AIDS must integrate prevention with care and treatment.[30] This was a tacit rejection of the WHO's initial

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[28] David R. Holtgrave, *Causes of Decline in AIDS Deaths, United States, 1999-2002: Prevention, Treatment or both?* (2005) 16:12 International Journal of STD & AIDS 777.

[29] Centers for Disease Control and Prevention, *HIV/AIDS Surveillance Report: US Cases of HIV and AIDS in the United States, 2002*. Year end edition, vol. 41, p. 5. See also John M. Karon, *et al., HIV in the United States at the turn of the Century: An Epidemic in Transition* (2001) 91 Am J Public Health 1060- 1068.

[30] Alan Berkman, *et al., A Critical Analysis of the Brazilian Response to HIV/AIDS: Lessons Learned for Controlling and Mitigating the Epidemic in Developing Countries* (2005) 95:7 Am J Public Health 1162.

policy of prevention and control, which has now proved ineffective in most resource-poor settings (with the exception of Uganda and Thailand) going by the steady rise in AIDS figures emanating from developing countries. Because of this fact, policymakers and researchers consistently called for an international paradigm that focuses on treatment.[31]

The success of this mode of response in Brazil has intensified the demand for a policy change in developing countries. Brazil is a developing country with a fairly substantial number of AIDS patients.[32] It also shares, with other developing countries, a relative lack of social infrastructure and social inequality.[33] Despite Brazil's limitations, it has managed to cater for its AIDS afflicted population through its *National AIDS Programme* ('NAP').[34] This programme has integrated treatment with prevention. The integration of treatment and care was fundamental to the Brazilian programme even before the development of effective antiretroviral treatment.[35]

The State of Sao Paulo made small quantity of AZT available, at no cost, to its residents upon its introduction to the market in 1996.[36] Other states and, subsequently the Brazilian federal government copied this. Berkman, *et al*, hold the view that the governing factor for Brazil's success in its AIDS programme is its local

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[31] *Ibid.*

[32] The World Health Organisation estimates that around one third of all people living with HIV in Latin America reside in Brazil. In 2005, an estimated 620,000 people were living with HIV in Brazil. See World Health Organisation and Joint United Nations Programme on AIDS, *AIDS Epidemic Update*, December 2007. Online: UNAIDS/WHO, <http://data.unaids.org/pub/EPISlides/2007/2007_epiupdate_en.pdf>. (Accessed November 28, 2007).

[33] Richard Parker, *et al., The Brazilian Response to HIV/AIDS: Assessing its Transferability* (2003) 27 Debate 140-142.

[34] National Coordination for STD and AIDS, *The Brazilian Response to HIV/AIDS* (Brasilia: Ministry of Health, 2000).

[35] *Supra*, note 30 at 1170.

[36] *Ibid*

manufacturing capacity.[37] In their opinion, the Brazilian programme of universal, free access to antiretroviral is financially viable in large measure because of Brazil's capacity for local manufacture of generic pharmaceuticals.

The effectiveness of the treatment intervention in other developing countries has been the subject of some studies shortly after the marketing of AZT, the first antiretroviral, in 1996.[38] One of such studies[39] concluded that though the use of antiretroviral is desirable, the cost of the drugs has made the treatment inaccessible to most of those infected.[40] However, unlike Brazil and the US (both with proven manufacturing capabilities), most developing countries lack drug production technology. Ultimately, poor countries will have to purchase the needed drugs from brand-name producers since they lack the means to manufacture locally. This has been the problem with the treatment intervention in economically disadvantaged countries of the world. When this problem is expressed in a treatment perspective, the lack of access to affordable antiretrovirals for the infected becomes one of the challenges facing developing countries.

Standard antiretroviral therapy consists of the use of at least three antiretrovirals to maximally suppress the HIV virus and stop the progression of the disease in the body.[41] Combination therapy, which involves taking two or more types

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[37] *Ibid.*

[38] Robert Hogg & Katherine Heath, *et al., Improved Survival among HIV-infected individuals following initiation of antiretroviral therapy* (1998) 279:6 JAMA 450-455. See also Robert Hogg, *et al., Antiviral Effect on double and triple drug combinations among HIV infected adults: Lessons from the implementation of viral-load driven antiretroviral therapy* (1998) 12:3 AIDS 279-284.

[39] Evan Wood, *et al., Extent to which low-level use of antiretroviral treatment could curb the AIDS Epidemic in sub-Saharan Africa* (2000) 355: 9221Lancet 2095

[40] See, also on this point, Robert Hogg & Amy Weber, *et al., One World, One Hope: The Cost of Providing Antiretrovirals to all Nations* (1998) 12:16 AIDS 2203- 2209.

[41] World Health Organisation, *HIV/AIDS: Antiretroviral Therapy*, online: WHO <http://www.who.int/hiv/treatment/en/index.html >

of antiretrovirals at every interval of usage, makes AIDS treatment costly for the poor, low and middle-income level patients in developing countries.[42] At present, a combination of patented antiretrovirals costs between US$10,000- $15,000 per patient a year in many developing countries.[43] This indeed is a high amount for poor patients to afford in developing countries where, according to WHO, an estimated 6.5 million infected people lack access to antiretrovirals.[44]

1.4 A Global Access Revolution

A recent study has confirmed the effectiveness of combination antiretroviral regimens in preventing AIDS-related illness and death.[45] The task, however, concerns creating access to these therapies for the people living with HIV in developing countries. A 2004 report had suggested that, "the high price of many of the HIV-related medicines and diagnostics offered by common suppliers-especially antiretroviral and anti-cancer medicines- is one of the main barriers to their availability in developing countries."[46] The demand that the world should act fast in scaling up access to ARVs in developing countries had led, in 2001, to the introduction of a policy- *Declaration on Commitment on HIV/AIDS*- unanimously

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[42] Pascale Boulet, Christopher Garrison & Ellen 't Hoen, *Drug Patents under the Spotlight: Sharing Practical Knowledge about Pharmaceutical Patents* (Geneva: Medecins Sans Frontieres, 2004) p. 14.
[43] Oliver Razum & Sylvia Okoye, *Affordable Antiretroviral Drugs for Developing countries: Dreams of the Magic bullet* (2001) 6 Tropical Medicine and International Health 421.
[44] Avert, *Introduction to HIV/AIDS treatment*. Online: <http://www.avert.org/introtrt.htm>
[45] Ellie Carmody, Theresa Diaz & Paulo Starling, *et al., An Evaluation of Antiretroviral HIV/AIDS Treatment in a Rio de Janeiro Public Clinic* (2003) 8:5 Tropical Medicine and International Health 378.
[46] UNAIDS, *2004 Report on the Global AIDS Epidemic*. Online: UNAIDS, <http://www.unaidsorg/en/media>

endorsed by the United Nations General Assembly.[47] With this came the "3 by 5" initiative.[48]

Despite these efforts at the international level, the number of people still without access to antiretrovirals in the developing world is alarming.[49] Developing countries and some experts have identified the WTO[50] rules on intellectual property- specifically the rules on pharmaceutical patents- as the major impediment to accessing affordable antiretroviral therapy in the developing world.[51]

1.5 Chapter Summary

To set the tone for an analysis of access mechanisms presently in use, this chapter has examined strategies adopted by the WHO for tackling HIV/AIDS scourge, beginning from its inception. Strategies such as prevention and control, and subsequently treatment, have been employed by the WHO particularly in the fight against HIV. Reliance on a treatment initiative more than prevention, owing to the near impracticability of abstinence in present times, has led to demands for more affordable medicines to meet the goal of treating three million HIV/AIDS patients by 2005 ("3 by 5"). In the following section, factors militating against achieving this goal are examined.

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[47] See Cameron & Gupta, *supra* note 19.
[48] *Supra* note 2.
[49] *Supra* note 44.
[50] The WTO is the only international organisation dealing with the rules of trade between nations. It was established on 1 January 1995, after eight years of rounds of negotiations (the Uruguay Round Agreement of 1986-1994). See *WTO in Brief*, online: WTO <http://www.wto.org/english/thewto_e/whatis_e.htm > (accessed 5 February 2007).
[51] John Barton & Ezekiel Emmanuel, *The Patent-based Pharmaceutical development Process: Rationale, Problems and Potential reforms* (2005) 294:16 JAMA 2075.

PART II

BARRIERS TO ACCESS

2.1 Introduction

The issue of access to affordable pharmaceuticals has been of a great concern to developing countries whose health-care systems are already overwhelmed by HIV/AIDS and other infectious diseases.[52] A global legal response came by way of TRIPs. Even then, debate about TRIPs has been two-sided. On one side, some developing countries see the TRIPS agreement as an impediment in their attempts to combat public health emergencies by restricting drug availability and by transferring scarce resources from developing countries to manufacturers in developed countries, via high prices of drugs.[53] Still others have contended that the introduction of patents into the developing world restricts sustainable development and perpetuates their dependence upon developed nations.[54]

On the other side, manufacturers in developed countries view the TRIPs agreement as essential to encourage innovation in the pharmaceutical sector by assuring international compensation for their intellectual property.[55] It is also believed that the introduction of full-fledged patent system around the globe will provide needed incentives for investment and innovation.[56] Without the intellectual property rights guaranteed under TRIPs, the pharmaceutical industry claims it could

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[52] *Supra*, note 10.

[53] *Integrating Intellectual Property and Development Policy*, UK Commission on Intellectual Property (CIPR), September 2002, p. 41.

[54] Samuel A Oddi, *TRIPs- Natural Rights and a 'Polite Form of Economic Imperialism'* (1996) 29 Vand. J. Transnat'l L. 415.

[55] Pharmaceutical Research and Manufacturers of America, *Intellectual Property.* Online: PhRMA, <http://www.phrma.org/issues/intprop> (accessed 6 February 2007).

[56] Evelyn Su, *The Winners and the Losers: The Agreement on Trade-Related Aspects of Intellectual Property Rights and Its Effects on Developing Countries* (2000) 23 Hous. J. Int'l L. 169.

not recoup the high cost of developing medicines because developing countries are hubs for piracy activities, having not introduced legal mechanism to deal with piracy.[57] This appears to buttress the point raised by some developing countries that TRIPs is a product of pressure from developed countries to secure intellectual property rights in developing countries[58] and that the view that TRIPs is for technology transfer is a ruse.[59]

Although these arguments do not constitute a core of this paper, attempt shall however be made to briefly discuss some of the barriers to access to drugs. The barriers are: TRIPs-related and non-TRIPs related.

2.2 TRIPs related Barriers

2.2.1 Pharmaceutical Patents

A patent "is a statutory grant which confers on an inventor or his legal successor, in return for the disclosure of the invention to the public, the right to exclude others from using the invention for a limited period of time."[60] To qualify as a patentable subject matter, an invention (which may be a product or a process) must be "...new, involve an inventive step and (be) ... capable of industrial application."[61] TRIPs further provides that with respect to Article 27.1, "the terms 'inventive step' and 'capable of industrial application' may be deemed by a Member to be

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[57] United States International Trade Commission, *Foreign Protection of Intellectual Property Rights and the Effects on the US industry and trade*, 1988. Publication No. 2065

[58] Jeffrey Atik & Hans Henrik Lidgard, *Embracing Price Discrimination: TRIPS and the Suppression of Parallel Trade in Pharmaceuticals* (2006) 27 U. Pa. J. Int'l Econ. L. 1044.

[59] Article 66.2 mandates developed country members of the WTO to provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least developed country members in order to enable them to create a sound and viable technology base. There is no mention of developing country members in this sub-section.

[60] Ernst Jucker, *Patents and Pharmaceuticals* (Basle: Buchdruckerei Gasser & Cie AG, 1980) p. 16.

[61] TRIPs, article 27.1

synonymous with the terms 'non-obvious' and 'useful' respectively."[62] Therefore in accordance with Article 27.1, a patent will normally be granted if an invention conforms to the requirements of novelty, inventive step, and industrial applicability.

In the pharmaceutical industry (including other industries), patents create a temporary monopoly for a twenty-year period over patented pharmaceuticals, thereby permitting the patent-holder to charge whatever price it deemed fit on patented drugs.[63] The patent protection on a drug may extend to any other improved version or process of the same drug.[64] Although patent as an intellectual property right predates AIDS and antiretrovirals[65], its connection with the issue of access to the latter began with the coming into effect of the TRIPs agreement in 1995.

TRIPs permits all WTO member countries to adopt "certain minimum standards for protection of private intellectual property rights", including pharmaceutical inventions.[66] Pharmaceutical companies generally rely on Article 27.1 of TRIPs to obtain patents, in countries other than their home countries, for their products since that provision imposes on all members of the WTO, an obligation by which "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application". TRIPs guarantees such patent protection for all

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[62] Foot note 4, Article 27.1 of TRIPs.
[63] Boulet *et al.*, *supra* note 42 at 2.
[64] The Rt. Hon. Sir Robin Jacob, Daniel Alexander & Lindsay Lane, *A Guidebook to Intellectual Property: Patents, Trade Marks, Copyright and Designs*, 5th ed. (London: Sweet & Maxwell, 2004) p. 18
[65] Some texts trace its origin to 1421 when the city of Florence issued a patent to Filippo Brunelleschi on his invention of a new type of ship. See Aaron Schwabach, *Intellectual Property* (California: ABC-CLIO, Inc., 2007) p.12; Allen Nard & Andrew Morriss, *Constitutionalizing Patents: From Venice to Philadelphia*, 2004. Case Research Paper Series in Legal Studies, Working Paper 04-12. <http://ssrn.com/abstract=585661>
[66] See TRIPs, paras (a), (b) and (c).

inventions for twenty years, beginning from the date of first filling.[67] This is an adoption of the United States- style patent systems that apply both to products and processes, and also last for twenty years.[68] The twenty year period is to compensate for the delays usually experienced by drug and other products producers when securing regulatory approval before the domestic sale of such products.[69]

Different types of pharmaceutical patents have been identified as being operational in developing countries.[70] These are: *Product patents* (covering the pharmacologically active chemical or formulation), *Process patents* (covering a manufacturing process for the same) and *Use patents* (covering the use of a drug for a medical indication). All these confer a degree of market exclusivity (i.e., an exclusive right to manufacture and sell the patented product).

2.2.2 Rationales for the Grant of Patent Protection

The justifications for grant of patent on products, processes and uses can be categorized into two broad classes. There are the 'incentive theory' and the 'natural right' arguments. The incentive theory has two ambits. There is the incentive to invent and innovate and the incentive to disclose trade secrets. In the context of pharmaceutical patent, an incentive to invent and innovate rather than disclose trade secrets seems to be an overriding justification for the grant of patents. By an incentive to invent theory, proponents view the patent system, and its key feature of

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[67] TRIPS, Article 33.
[68] Robert Weissman, *AIDS and Developing Countries: Democratising Access to Essential Medicines* Online: Foreign Policy in Focus <http://www.fpif.org > (accessed 6 February 2007)
[69] Trevor Cook, *A User's Guide to Patents* (London: Butterworth Lexis Nexis, 2002) p. 272.
[70] Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?* (2001) 286 JAMA 1886 at 1887.

monopoly, as providing incentives for individuals to engage in innovative ventures.[71] "Without the prospect of an exclusive right to use the invention (and a possibility of recouping the money invested in the development of the invention), investments in research and development would not be attractive enough and too little inventing would be done."[72] The theorists of this incentive to invent and innovate contend that absent a patent system, inventions could be easily duplicated or exploited by other people- also known as free riders- who would have incurred no cost to develop and perfect the idea involved, and who could thus undersell the inventor.[73]

Following from above theory, the pharmaceutical industry observes that prices of medicines are necessarily high because medical innovation is expensive.[74] As a result of this, the research and development ('R&D') enterprise must be nurtured by high prices to yield the next generation of breakthrough therapies. The principal voice behind this view, the Pharmaceutical Research and Manufacturers of America ('PhRMA')[75], opines that it takes 10-15 years and cost $800 million on

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[71] Roger E. Schechter & John R. Thomas, *Principles of Patent Law* (Minnesota: Thomson West, 2004) p.9

[72] Sigrid Sterckx, "The Ethics of Patenting- Uneasy Justifications" in Peter Drahos, ed., *Death of Patents* (London: Lawtext Publishing Limited, 2005) p.193

[73] *Ibid*, p. 10. See also Rebecca Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use* (1989) 56 U. Chi. L. Rev. 1017.

[74] Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets* (2005) 5 Yale J. Health Pol'y, L & Ethics 193-194.

[75] The PhRMA is the U.S trade association for research pharmaceutical and biotechnology companies. See <http://www.phrma.org/about_phrma/> (accessed 6 February 2007). Generic drug companies have their own trade associations, one of which is the Generic Pharmaceutical Association, GPhA, a US body, see <http://www.gphaonline.com>. The international version is the International Generic Pharmaceutical Alliance which comprises the European Generic Medicines Association, the Canadian Generic Pharmaceutical Association, GPhA and the Indian Pharmaceutical Alliance, IPhA. See <http://www.egagenerics.com/igpa.htm>. While the PhRMA canvasses patent protection as encouragement for more research and development, the IGPA lobbies WTO, WHO and WIPO to adopt regulatory flexibility in the generic production of patented drugs as a measure to ensure access to affordable drugs in the poor regions of the world.

average to bring a new medicine to the market.[76] This argument has however been countered. According to the opposing view, much of the profits going to pharmaceutical companies are used for marketing and other expenses rather than for R&D.[77]

There is also the incentive to disclose; which is premised on the desirability for public disclosure of an invention. Patent historians claim that the rise of the patent system is traceable to the demise of trade guilds as protectors of sensitive technology.[78]

> At the close of the feudal period, trade guilds required years of apprenticeship to earn access to proprietary secrets. These guilds restricted distribution of trade secrets to members of the guilds. Although this practice prevented free-riding, the high barrier to entry… discouraged competition and impeded scientific advance… The public patent grant removed those artificial barriers. In exchange for disclosure in the patent application, the inventor received a limited period of exclusive rights.[79]

The patent system, as an incentive to disclose trade secrets, encourages inventors to disclose their inventions instead of keeping them secret. Inventors have to disclose sufficient information about their invention in order to obtain patent protection. Technological information is spread, making technological progress possible. Advocates of the incentive to disclose argument describe the granting of

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[76] Pharmaceutical Research and Manufacturers of America, *Intellectual Property.* Online: PhRMA, <http://www.phrma.org/index.php?option=com> (accessed 6 February 2007).

[77] Ellen 't Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha* (2002) 3 Chicago J. Int'l L. 29

[78] Martin Adelman, Randall Rader & Gordon Klancnik, *Patent Law* (Minnesota: Thomson-West, 2008)

[79] *Ibid* at p.6. However, a critic of this incentive- to- innovate rationale argues that by its very nature, the patent system promotes secrecy rather than enable a full disclosure of the technology behind the invention for society's use. See David Vaver, *Intellectual Property Law: Copyright, Patents, Trademarks* (Ontario: Irwin Law, 1997) p.7. Vaver opines that patents are supposed to encourage work to be disclosed to the public and to increase society's pool of ideas and knowledge by making clinical data and the mechanisms of the inventions accessible to other researchers after the duration of the patent.

patents as a social contract between the society and the inventor: "society gives the inventor a temporary monopoly in return for which the inventor discloses his secrets."[80]

However, the incentive to disclose has been criticized as discouraging rather than encouraging inventions and innovations. According to Sterckx, patent granting authorities do not often take seriously the requirement of sufficiency of disclosure. As such "patents with unduly broad claims are granted."[81] The incentive to invent argument spurs pharmaceutical invention much more than the incentive to disclose in that the former relates more to what has being termed "self-disclosing inventions susceptible to reverse engineering-such as pharmaceutical products."[82] On the other hand, incentive to disclose encourages the "non self-disclosing kind."[83]

In contrast to the incentive theory, the natural rights school posits that persons have a natural right of property in their labour. The most celebrated proponent of this theory is the philosopher, John Locke. Locke asserts that individuals should enjoy a property entitlement to the products of their labour, and innovators too should be entitled to enjoy the fruits of their labour by being granted an exclusive right in their works.[84]

The failure of the current patent-based drug development system can be said to be internally generated. First, recovering research costs through a patent monopoly

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[80] See Sterckx; *supra* note 72 at 198-199.

[81] Sigrid Sterckx, "European Patent Law and Biotechnological Inventions" in Sigrid Sterckx (ed.) *Biotechnology, Patents and Morality*, 2nd Ed. (Aldershot: Ashgate, 2000) pp.21-25.

[82] Cameron Hutchison, *Over 5 Billion Not Served: The TRIPs Compulsory Licensing Export Restriction.*
Available online at <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1012625>

[83] *Ibid*

[84] Peter Laslett, ed., *John Locke's Two Treatises of Government*, 2d ed, 1967; Wendy Lim, *Towards Developing a Natural Law Jurisprudence in the US Patent System* (2003) 19 Santa Clara Computer & High Tech. L. J. 559.

intensifies the tension between the research goals and the accessibility goals.[85] The more money spent on research, the higher the drug price required to recover the costs- yet higher prices limit access to the innovative products.[86] Where the pharmaceutical innovation is a blockbuster drug (ARVs mostly are), pharmaceutical industry experts reckon that each month of exclusivity would be worth $100 million or more, in profit, to the manufacturer.[87]

Second, a misallocation of resources exists between research and marketing. According to pharmaceutical industry publications,[88] promotional costs, including the value of samples amount to about 60% of the research expenses. Statistics from the 10 largest pharmaceutical companies further amplify this fact: 13.7% of revenue is devoted to research and development, while 34.4% goes to marketing, general and administrative costs, 29.4% to product manufacturing costs, and 23.6% to pretax profits.[89] While administration, manufacturing and marketing are necessary, the proportion of production costs allocated to them seem excessive compared to research costs. Scherer therefore argues that firms allocate more money to marketing because it yields greater returns than research on new drugs.[90]

Uncharacteristically, in its *Pharmaceutical Industry Profile 2005*, the PhRMA observed that the overall level of investment in the drug development

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[85] Mike Scherer, *The Pharmaceutical Industry- Prices and Progress* (2004) 351 N Engl J Med. 927-932.
[86] *Ibid.*
[87] *Supra* note 51 at 2076.
[88] Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry Profile 2005* (Washington, DC: PhRMA, March 2005). Also available online at <http://www.phrma.org/files/2005IndustryReport.pdf> (Accessed 17 October 2007); See also Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry Profile 2002* (Washington, DC: PhRMA, 2002)
[89] Joseph DiMasi, *et al., The Price of Innovation: New Estimates of Drug Development costs* (2003) 22 J. Health Econ. 151.
[90] *Supra* note 85 at 930.

process actually seems low, given the huge profits. A study undertaken by the group indicates that "the financial return from pharmaceutical research has followed an inverted U-shaped curve."[91] In the 1970s, the percentage of sales spent on research was approximately 12.5%. It peaked at 22% in 1994 and has decreased to about 18% of sales in 2003. Consequently, the pharmaceutical industry develops profitable drugs for the wealthy regions of the world, and makes its biggest profits from hair tonics, anti-impotency drugs, and drugs for cholesterol, ulcers, depressions, allergies and high blood pressure.[92]

Notwithstanding the strong arguments in support of patent protection for medicines, objectors to pharmaceutical patents claim that monopoly pricing, aided by patents, makes ARVs unaffordable to those who need them in developing countries.[93] There is empirical evidence to back up both sides of this debate. The first of these strengthens the case for patent protection. Two studies by Amir Attaran (assisted by Lee Gillespie- White in the first of the studies) are on this point.[94] Meanwhile, a host of experts hold the view that compelling data strongly indicate patents play a significant role in hindering access to ARVs in developing countries.[95]

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[91] *Supra* note 88.

[92] Sigrid Sterckx, *Patents and Access to Drugs in Developing Countries: An Ethical Analysis* (2004) 4:1 Developing World Bioethics, pp.58-75 at 69.

[93] Michael Selgelid & Eline Sepers, "Patents, Profits, and the Price of Pills: Implications for Access and Availability" in Jillian Cohen, Patricia Illingworth & Udo Schuklenk, eds, *The Power of Pills: Social, Ethical and Legal Issues in Drug Development, Marketing and Pricing* (London: Pluto Press, 2006) at 156.

[94] *Supra* note 70.

[95] Marleen Boelaert, Lut Lynen, Wim Van Damme & Robert Colebunders, *Do Patents Prevent Access to Drugs for HIV in Developing Countries?* (2002) 287 JAMA 840-841; Eric Goemaere, Anne- Valerie Kaninda, Laura Ciaffi, Maryline Mulemba, Ellen 't Hoen & Bernard Pecoul, *Do Patents Prevent Access to Drugs for HIV in Developing Countries?* (2002) 287 JAMA 841-842 and Consumer Project on Technology, *Comment on Attaran/Gillespie-White and PhRMA Surveys of Patents on Antiretroviral Drugs in Africa,* 2001, Washington, DC, online: CPT <http://www.cptech.org/ip/health/africa/dopatentsmatterinafrica.html> (accessed March 30, 2007)

(i) Poverty as a factor

A study jointly funded by the Center for International Development at Harvard University and the World Intellectual Property Organisation (WIPO), and conducted by Dr. Amir Attaran and Ms Lee Gillespie-White, in 2001, concluded that "it is doubtful that patents are to blame for the lack of access to antiretroviral drug treatment in most African countries...other factors, and especially the ubiquitous poverty of Africa countries, must be more to blame."[96] Attaran and Gillespie-White collated data on 15 available ARVs and similar legal rights of which 8 participating pharmaceutical companies had knowledge in 53 African countries.

Perhaps the most frequently offered argument from supporters of global pharmaceutical companies is that the big problem is not patent but poverty. Industry-supported American think tanks such as the American Enterprise Institute, the International Intellectual Property Institute (IIPI) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) have also popularised this view.[97]

In the second, more recent study, Attaran examined the extent to which essential medications are patented in developing countries more generally. The study reveals that:

> In sixty-five low-and middle-income countries, where four billion people live, patenting is rare for [the] 319 products on the World Health Organization's Model List of Essential Medicines. Only seventeen essential medicines are patentable, although usually not

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[96] Attaran & Gillespie- White 2001, *supra* note 70 at 1890.

[97] Eric Noehrenberg, *Report of the Commission on Intellectual Property Rights, Innovation and Public and Public Health: An industry Perspective* (2006) 84 Bull. World Health Org. 419; IFPMA, *WHO Commission Report on Biomedical Innovation, Patents and Public Health Contains many Sound Proposals but Mistakenly Underestimates the Vital Role of Patents*, April 3, 2006. Online: IFPMA, <http://www.ifpma.org/News/NewsReleaseDetail.aspx?nID=3D4628>

> actually patented, so that overall patent incidence is low... I find that patents for essential medicines are uncommon in poor countries and cannot readily explain why access to those medicines is often lacking, suggesting that poverty, not patents, imposes the greater limitation on access.[98]

Attaran & Gillespie-White state further "because geographic patent coverage [did] not appear to correlate with anti-retroviral treatment access in Africa, patents and patent law are not a major barrier to treatment access in and of themselves."[99]

(ii) Patent hinders Access: Responses to Attaran & Gillespie-White

There has been widespread criticism of these studies by experts in the field.[100] In one of the responses, it was argued that the earlier study failed significantly to acknowledge that not all existing AIDS drugs are equally important in treating the disease.[101] Experts claim that treatment experience in Africa shows that the conclusion reached by Attaran & Gillespie-White is meaningless if the drug combination required for effective therapy in a particular context are not considered.[102]

Lamivudine and Zidovudine are, for instance, central to AIDS treatment, representing 60% of nucleoside reverse transcriptase inhibitor sales in major pharmaceutical markets.[103] These experts revealed that AIDS treatment programmes in most African countries use Lamivudine, Zidovudine and Nevirapine (or a

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[98] Amir Attaran, *How do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?* (2004) 23 Health Affairs 155-166.
[99] Attaran & Gillespie-White, *supra* note 70.
[100] *Supra* note 95.
[101] See Selgelid & Sepers, *supra* note 93.
[102] Eric Goemaere, Anne- Valerie Kaninda, Laura Ciaffi, Maryline Mulemba, Ellen 't Hoen & Bernard Pecoul, *Do Patents Prevent Access to Drugs for HIV in Developing Countries?* (2002) 287 JAMA 841-842
[103] *Ibid.*

combination of any three antiretrovirals) commonly referred to as highly active antiretroviral therapy ('HAART') to treat the disease.[104] Although, HAART sometimes exceed $20,000 per year, and is thus not readily available to over 95% of the estimated 39.5 million infected people worldwide[105], they nevertheless make treatment feasible because they can be taken once or twice daily without dietary requirements. Single or dual therapy needs to be taken under strict dietary prescription.[106]

Clinical studies in developed and developing countries have confirmed the advantage a HAART regimen has over a single or dual therapy regimen.[107] One of such studies carried out in Switzerland found a low 15 % progression to death rate for AIDS patients placed on HAART as against a very high 95 % progression to death rate for AIDS patients on a dual therapy.[108] A similar study in Spain disclosed the efficacy of HAART over single or dual therapy. In Spain, where AIDS patients have free access to ARVs, HAART has dramatically reduced health inequalities.[109] Tests conducted in southern African countries also confirmed the vast potentials of

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[104] See also Boelaert, *et al*, *supra* note 95.

[105] Carrasco, *et al., supra* note 24 at 315.

[106] Edwin DeJesus & Debra McCarty, *et al., Once Daily versus Twice Daily Lamivudine, in combination with Zidovudine and Efavirenz, for the Treatment of Antiretroviral-naive Adults with HIV Infection: A Randomised Equivalence Trial* (2004) 39:3 Clin Infect Dis 411-418.

[107] This fact has been proved in the US where a high number of deaths arising from AIDS were prevented due to the use of HAART. See, on this point, Centers for Disease Control and Prevention and John M. Karon, *et al., supra* note 29.

[108] Jonathan AC Sterne, Miguel A Hernan & Bruno Ledergerber, *et al., Long- time Effectiveness of Potent Antiretroviral therapy in Preventing AIDS and Death: A Prospective Cohort Study* (2005) 366: 9483 Lancet 378-384.

[109] Sam Harper & John Lynch, *Highly Active Antiretroviral Therapy and Socioeconomic Inequalities in Spain* (2007) 17:2 Eur. J. Public Health 231. See also Andrew M Hill & Colette Smith, *Analysis of Treatment Costs for HIV RNA Reductions and CD4 Increases for Darunavir Versus other Antiretrovirals in Treatment-Experienced, HIV-infected Patients* (2007) 8:3 HIV Clinical Trials 121-131; Frank J Palella & Rose K Baker, *et al., Mortality in the Highly Active Antiretroviral Therapy Era: Changing Causes of Death and Diseases in the HIV Outpatient Study* (2006) 43:1 J Acquir Immune Defic Syndr 27-34.

HAART in Africa if regular access to the drugs is guaranteed.[110] When patients in resource-poor settings in developing countries are able to access HAART, treatment adherence has been reported to be comparable to industrialized countries.[111]

Unfortunately, this set of important ARVs is patented in three quarters (37 out of 53) of countries surveyed by Attaran & Gillespie-White in Africa, representing 81% of Africa's AIDS burden.[112] This means that these drugs are three times more expensive than the quality generic medication in South Africa.[113] The direct impact of patents on AIDS treatment is enormous in South Africa where, for instance, in a pilot project only 85 out of a targeted 185 infected persons could receive HAART in Khayelitsha Township due, primarily due to the high cost of the drugs.[114]

In sharp contrast to HAART, many of the non-patented single or dual antiretroviral drugs are "therapeutically impractical in resource poor settings because of adverse effects (which require adequate monitoring capacity) and cumbersome

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[110] Adamson S Muula & Thabale J Ngulube, *Gender Distribution of Adult Patients on Highly Active Antiretroviral Therapy (HAART) in Southern Africa: A Systematic Review* (2007) 7:63 BMC Public Health.

[111] Chitra Akileswaran, Mark Lurie, Timothy Flanagin & Kenneth Mayer, *Lessons learned from use of Highly Active Antiretroviral Therapy in Africa* (2005) 41:3 Clin Infect Dis 376- 385.

[112] Joint United Nations Programme on HIV/AIDS: *Table of Country-Specific HIV/AIDS Estimates and Data*, online: UNAIDS <http://www.unaids.org/epidemic_update/report/#table>

[113] Carmen Perez-Casas & Cecile Mace, *et al., Accessing ARVs: Untangling the Web of Price Reductions for Developing Countries*, online: MSF <http://www.globaltreatmentaccess.org/content/press_releases/01/100501_MSF_RPT_ARV_prices.pdf>

[114] The exorbitant prices of antiretrovirals in Africa once prompted Mr. Justice Edwin Cameron of the High Court of Johannesburg, South Africa to say this, "I can take these tablets, because on the salary I earn as a Judge, I am able to afford their cost… In this I exist as a living embodiment of the inequity of drug availability and access in Africa… My presence here embodies the injustice of AIDS in Africa because, on a continent in which 290 million Africans survive on less than one US dollar a day, I can afford monthly medication costs of about US$400 per month." See Sonia Ehrlich Sachs & Jeffrey D Sachs, "Too Poor to Stay Alive" in Kyle D Kauffman & David L Lindauer, eds., *AIDS and South Africa: The Social Expression of a Pandemic* (Palgrave: Macmillan, 2004).

dietary requirements."[115] Again, the quantitative approach taken by Attaran and Gillespie- White is misleading because the most effective combinations of antiretroviral medication are in fact blocked in a large number of African countries.[116] By this, it is meant that most of the antiretrovirals that could be combined as HAART are patented in countries in Africa.

Furthermore, Attaran and Gillespie-White failed, in their studies, to appreciate the extent to which patents on drugs in one country could have adverse access implications for other countries within the same region.[117] South Africa, for instance, is the country with the largest number of HIV-positive persons worldwide[118] and possesses production capacity for generic medicines. But patent protection for the essential antiretrovirals in that country means that other African countries like Botswana and Zimbabwe that depend on South Africa for cheap drugs can not access those cheap drugs.[119] It is a fact that "patents do matter- they have caused and are still causing significant delays in providing appropriate medications, especially in South Africa."[120]

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[115] *Supra* note 95.

[116] Consumer Project on Technology, *Comment on Attaran/Gillespie-White and PhRMA Surveys of Patents on Antiretroviral Drugs in Africa,* 2001, Washington, DC, online: CPT <http://www.cptech.org/ip/health/africa/dopatentsmatterinafrica.html> (accessed March 30, 2007)

[117] Michael Selgelid & Udo Schuklenk, *Do Patents Prevent Access to Drugs for HIV in Developing Countries?* (2002) 287 JAMA 842-843.

[118] The figure is currently put at 5.5 million. See UNAIDS, *Uniting the World against AIDS*, online: UNAIDS http://www.unaids.org/en/Regions_Countries/Countries/south_africa.asp (accessed March 30, 2007).

[119] For instance, owing to the high cost of ARVs in resource-poor countries, some analysts have suggested distribution of free ARVs. See Donald Berwick, *We all have AIDS: Case for reducing the cost of HIV Drugs to zero* (2002) 324:7331 BMJ 214 -218; Ken Bluestone, *Safeguarding Developing Countries' Rights to Affordable Medicines for HIV/AIDS: How Effective are International Trade Rules?* (2001) 6:3 Trop Med Int Health 161-162; Gavin Yamey & William Rankin, *AIDS and Global Justice* (2002) 324:7331 BMJ 181- 82.

[120] Boelaert, *et al.*, *supra* note 95.

2.2.3 Expiration of TRIPS Transitional Periods for Pharmaceuticals

Apart from allowing for the possibility of globalising patent protection for pharmaceuticals, TRIPs set timelines for member countries of the WTO to fully incorporate intellectual property protection for products and processes in their domestic legislation. The various patent portions of TRIPs feature a variety of effective dates; these dates depend upon whether a WTO member state is designated a developed, developing[121] or least developed country (LDC).[122] For WTO members other than developing and least developed countries, the compliance date for all requirements of TRIPs was set at January 1, 1996.[123] Least developed countries have had a lengthy transition period in implementing TRIPs. Article 66.1 of TRIPs permits least developed country Members of WTO to postpone compliance with TRIPs for a period of ten years from the date of application as defined under paragraph 1 of Article 65. This gives the least developed country Members a break

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[121] The classification of countries into developed, developing and least developed does not follow a particular pattern. Whereas the WTO uses the designation 'least developed countries' as a term of art to refer to the poorest nations of the world, member nations of the WTO are at liberty to announce for themselves whether they fall within the 'developing country' category, and other member nations may challenge any such self-designation if they think it inappropriate. See Schechter & Thomas, *supra* note 71 at pp. 400- 401. See also the World Bank system of designation, *supra* note 11. The Economic and Social Council of the United Nations, in its 2003 triennial review, defined an LDC on the basis of three indicators of: (a) low- income level based on a 3-year average estimate of the gross national income (GNI) per capita; (b) a human resource weakness criterion, involving a composite Human Assets Index (HAI) based on indicators of nutrition, health, education and adult literacy; and (c) an economic vulnerability criterion, involving a composite Economic Vulnerability Index (EVI) based on indicators of: (1) the instability of agricultural production; (2) the instability of exports of goods and services; (3) the economic importance of non-traditional activities (share of manufacturing and modern services in GDP); (4) merchandise export concentration; and (5) the handicap of economic smallness (as measured through the population in logarithm); and the percentage of population displaced by natural disasters. See the UN Office of the High Representative for the Least Developed Countries, Landlocked Developing Countries and Small Island Developing States (UN-OHRLLS), *The Criteria for the Identification of the LDCs* (2003); Online <http://www.un.org/special-rep/ohrlls/ldc/ldc%20criteria.htm.> (Accessed 22 September 2007).

[122] Approximately 30 of the WTO member states are classified as 'least developed.' Some of the least developed countries in the WTO include Sierra Leone, Haiti and Bangladesh. For a full list, see WTO: <http://www.wto.org/english/thewto_e/whatis_e/tif_/org7_e.htm>

[123] TRIPs, Article 65.

from full implementation of TRIPs until January 1, 2016, only for pharmaceuticals. A showing of hardship may qualify least developed countries for further delays in implementation.[124]

However, it is not as easy for WTO signatory states that have classified themselves as developing countries. For the developing countries, TRIPs set the general compliance date as January 1, 2000.[125] There is one exception to this general date. If on January 1, 2000, a developing country did not extend patent protection to all areas of technology within the meaning of Article 27 of TRIPs, that developing country was permitted to delay implementation of these provisions for an additional five years.[126]

Prior to the advent of TRIPs many developing countries did not allow patents to issue on pharmaceuticals; the practical effect of this additional transitional period was that developing countries did not have to allow patents on pharmaceuticals until January 1, 2005.[127] But, commencing on that date, developing countries must implement every aspect of TRIPs including granting product, process and use patents on pharmaceuticals and other goods in their domestic markets.

As a result, leading generic manufacturing nations such as India (in Asia), South Africa (in Africa) and Brazil (in South America) became fully subject to

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[124] TRIPs, Article 66.1
[125] TRIPs, Article 65.2
[126] TRIPs, Article 65.4 provides that: "To the extent that a developing country member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that member, as defined in paragraph 2, it may delay the application of the provisions on product patents of section 5 of Part II to such areas of technology for an additional period of five years."
[127] Schechter & Thomas, *supra* note 71 at 401.

TRIPs, since they are self-designated as developing countries.[128] In particular, India's compliance with Article 65 presents a huge challenge to developing countries in that it is to date the primary exporter of affordable generic ARVs to other developing and least developed countries.[129] Under Article 65 of TRIPs, India and other non-developing countries had to grant domestic intellectual property protection for products and processes by January 1, 1996. To comply fully with Article 65 of TRIPs, India amended its *Patent Act, 1970* via the *Patents (Amendment) Act,* No. 15, 2005, to allow patenting of medicines in India.[130] This Act became operational on January 1, 2006.

2.3 Non-TRIPs related Barriers

2.3.1 Supplementary Protection Certificates

As established in Part II above, patent protection for pharmaceuticals had been introduced to protect the massive investments made by pharmaceutical companies, and to act as an incentive for further research. Despite this and the attendant hardships created in poor countries, the United States[131], Japan, Australia[132]

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[128] See Maria Oliveira & Jorge Bermudez, *et al., Has the Implementation of the TRIPs Agreement in Latin America and the Caribbean Produced Intellectual Property Legislation that favours Public Health?* (2004) 81:11 Bull. World Health Org. 815-821 at 815.

[129] For example, of the 700,000 people in developing countries estimated to be on ARV treatment, 50 percent are taking generics manufactured in India. See Ellen t' Hoen, *supra* note 77 at 55.

[130] The Gazette of India, Ministry of Law and Justice, *Patents (Amendment) Act, No. 15 of 2005.* Online: Indian Patent Office <http://www.patentoffice.nic.in/iprpatent/patent_2005.pdf> (accessed February 16 2007).

[131] In the US, this was introduced through the *Drug Price Competition and Patent Term Restoration (Waxman-Hatch) Act,* 42 U.S.C. 355 (1984).

[132] Wayne Condon, *Patent Term Extension for new Pharmaceutical Formulations in Australia,* online: Genericweb <http://www.genericsweb.com/index.php?object_id=345> (accessed April 3, 2007.)

and the European Community[133] have created supplementary protection certificates for medicinal products.

Supplementary Protection Certificate ('SPC') is a "special form of intellectual property that extends the protection of a patented active ingredient or combination of active ingredients present in a pharmaceutical or plant protection product after the expiry of the patent."[134] The only condition for the grant of an SPC specifies that the product or process must have a patent that is about to expire.[135] The grant of SPCs is growing at a relatively high rate in Europe. Statistically, the United Kingdom with 268 and Switzerland with 272 have issued the highest number of SPCs since its inception, followed closely by Belgium and Netherlands with 240 and 242 respectively.[136]

The justification for this scheme is that most of the term of a patent for a medicine may be exhausted before the safety authorities give permission to market.[137] Manufacturers of innovative drugs felt that the increasing delays attributable to increased regulation have reduced the effective patent term.[138] So the patentee may have spent a fortune yet have a very little time to recover his costs and make a profit.[139] The extension is usually for a maximum period of five years and it

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[133] See Council Regulation 1768/92 O.J. (L. 182) 1 (EC) and Directive 2001/83/EC.

[134] The United Kingdom Patent Office, *Supplementary Protection Certificates*. Online: UK Patent Office <http://www.patent.gov.uk/patent/p-other/p-object/p-object.spc.htm> (accessed February 19 2007). See also Gordon Wright, *Supplementary Protection Certificates: Advocate General Opinion on Formulations* (2006) 1 J. Intell. Prop. L. & P. 235.

[135] IMS Health Global Services, *What is a Supplementary Protection Certificate?* Online: <http://www.ims-global.com/insight/news_story/news_story_000417b.htm>

[136] *Ibid.*

[137] See Jacob, Alexander & Lane; *supra* note 64 at pp. 60-61.

[138] See Cook, *supra* note 69 at 308.

[139] *Supra* note 64.

comes into force after the basic patent expires,[140] thereby elongating the lifespan of patents on drugs from the twenty years permitted under TRIPs to twenty-five years.

In opposition to this, Canada filed a complaint at WTO alleging that the European Communities had adopted regulations that amounted to a scheme to extend patent terms on pharmaceuticals.[141] Despite this complaint and other international efforts against SPC[142], this practice is still in force. SPCs therefore have the potential of extending the patent rights of a patentee over a drug after the expiration of the TRIPs-recognised patent period.

2.3.2 United States Trade and Intellectual Property Policies

In the years following the introduction of TRIPs, the United States entered into a number of bilateral Free Trade Agreements (FTAs) with other nations.[143] Some of these Agreements are the US-Southern Africa Custom Union (SACU) Free Trade Negotiations,[144] the US-Central America Free Trade Agreement (US-CAFTA)[145] and the 2003 Singapore- United States FTA.[146] These Agreements have,

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[140] European Patent Office, *Supplementary Protection Certificates in INPADOC*, online: EPC <http://www.european-patent-office.orgnews/epidosnews/source/epd_2_01/ > (Accessed February 19 2007).

[141] European Community, *Patent Protection for Pharmaceutical and Agricultural Products, Complaint by Canada.* WT/DS153, 7 December 1998. See also *Canada Files WTO Complaint against EC* (2000) 5:4 HIV/AIDS Pol'y & L. Rev. 29

[142] The Spanish Government sought, unsuccessfully, to annul the SPC Regulation under the European Community Law. This resulted in the case- *Kingdom of Spain v. Council of the European Union* [1996] FSR 73; [1996] 1 CMLR 415.

[143] Office of the United States Trade Representative, *Trade Agreements*. Online: USTR, <http://www.ustr.gov/Trade_Agreements/Section_Index.html> (Accessed September 24, 2007)

[144] The Southern Africa Custom Union, SACU, comprises Lesotho, Namibia, Botswana, South Africa and Swaziland. UNAIDS ranks South Africa as having the most number of HIV/AIDS patients in the world; Botswana, Lesotho and Namibia have the highest, non-declining HIV prevalence in the world. See UNAIDS, *Report on the Global AIDS Epidemic 2006.* Online: UNAIDS, http://data.unaids.org/pub/GlobaReport/2006/2006_GR-ExecutiveSummary_en.pdf (Accessed September 27, 2007)

[145] Office of the United States Trade Representative, *US-Central America Free Trade Agreement: The Intellectual Property Provisions.* Report of the Industry Functional Advisory Committee on

to varying degrees, required their signatories to comply with patent standards that exceed the obligations of TRIPs Agreement.[147]

As an example, Article 16.7 of the Singapore-US FTA requires that Singapore extend the term of patents to compensate for unreasonable delays in patent acquisition proceedings and also places more restrictions upon the use of compulsory licenses than the TRIPs Agreement mandates.[148] Schechter & Thomas term these measures as 'TRIPs Plus'.[149] 'TRIPs Plus' refers to provisions in the national intellectual property legislation of some developed countries that either exceed the requirements of TRIPs or eliminate the flexibilities in implementing TRIPs.[150]

TRIPs Plus provisions usually inserted into these FTAs include: data exclusivity provisions, prohibition of parallel importation, linkage between drug registration and patent protection, highly restrictive conditions for issuing compulsory licenses, expanded subject matters requirements, and patent term extensions.[151] Of this lot, I will expatiate on only two to explain how US trade policies restrict access to drugs.

Intellectual Property Rights for Trade Policy Matters (IFAC-3). Online: USTR, <http://www.ustr.gov/new/fta/Cafta/advisor/ifac03.pdf>

[146] See Industrial Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters, *The US-Singapore Trade Agreement (FTA): The Intellectual Property Provisions*. Washington, DC: <http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Singapore_FTA/Reports/>

[147] Carlos Correa, *Investment Protection in Bilateral and Free Trade Agreements: Implications for the Granting of Compulsory Licenses* (2004) 26 Mich. J. Int'l L. 331; David Vivas- Eugui, *Regional and Bilateral Agreements and a TRIPs Plus World: The Free Trade Area of the Americas (FTAA)*. Quaker United Nations Office, Quaker International Affairs Programme, and International Center for Trade and Sustainable Development. <http://www.quno.org>

[148] *Supra* note 146.

[149] Schechter & Thomas, *supra* note 71 at 404.

[150] Susan K. Sell, *TRIPs- Plus Free Trade Agreements and Access to Medicines* (2007) 28:1 Liverpool Law Review 41-75 at 42.

[151] *Ibid* at 59.

Data exclusivity "refers to a practice whereby, for a fixed period of time, drug regulatory authorities do not allow the registration files of an originator to be used to register a therapeutically equivalent generic version of that medicine."[152] In most countries, innovative drugs are required to undergo long period of examination procedures before the grant of marketing approval, meant to ensure that the drugs are effective and safe for public consumption.[153] On the other hand, generic versions of the drug would require a less exhaustive examination procedure since they are generally approved as 'bioequivalence' of the original drug based on the clinical data already disclosed by the producer of the original drug as required under TRIPs.[154] In the light of the above, data exclusivity prevents a fast lane approach to generic drug approval and marketing.

The FTAs negotiated by the US require signatories to grant at least five years of data exclusivity on some products (usually medicines), counted from the date on which the product was approved, whether or not it was patented and whether or not the data was disclosed.[155] By negotiating data exclusivity, the US pandered to the wishes of brand name drug manufacturers who then use the FTAs as a ground for not complying with TRIPs which permits member countries to request brand name drug manufacturers to submit "undisclosed test or other data" in the process of granting marketing right for pharmaceutical, chemical or agricultural products.[156] The reason for requiring disclosure of such test or data, in the first place, is to assist generic drug

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[152] Milind Antani & Prashant Iyengar, *Towards a Law on Data Exclusivity*. Online: Pharmabiz, http://www.pharmabiz.com/article/detnews.asp?articleid=25566&sectionid=46 (Accessed December 30, 2007).
[153] *Ibid*
[154] TRIPs, Article 39.3.
[155] See Correa, *supra* 147 at 401.
[156] *Supra* note 154.

producers in easily producing the generic version of the drug upon the expiry of the patent on it.[157]

However, the data exclusivity provisions in FTAs are designed to require generic pharmaceutical producers to generate their own clinical trial test data, rather than rely on efficacy and safety findings of the brand name drugs in the generic drug approval process (which was expected to make generic process shorter and cost effective).[158]

Reichman has rightly pointed out that restricting the use of clinical trial data "could effectively empower rights holders to negate a state's ability to authorize marketing approval of equivalent drugs for a period for a period of five to ten years."[159] The ultimate outcome is that cheap generic drugs take much longer time to be manufactured, approved and sold. The US-CAFTA, like many other FTAs, has an extensive version of the data exclusivity provisions.[160]

To require the patent owner's consent for marketing approval for a patented drug, in the US FTAs, means that it will be nearly impossible to use compulsory licensing[161] as permitted by TRIPs.[162] Abbott concludes that, "even if a license is

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[157] Jerome H Reichman, *Undisclosed Clinical Trial Data Under the TRIPs Agreement and Its Progeny: A Broader Perspective* (2004) 1 IPRS. Online Publication available at <http://www.iprsonline.org>

[158] See Sell, *supra* note 150 at 60.

[159] See Reichman, *supra* note 157.

[160] US-CAFTA, Article 15.10 (1) (a) and (b). The US- Jordan FTA has it in its Article 4 (22) while the US- Singapore FTA embodies it in Article 16.7 and 16.8 (1-3). See Consumer Project on Technology, *Protection of Pharmaceutical Test Data*, online: CPTech, <http://www.cptech.org/ip/health/dataexcl/>

[161] For the purpose of this analysis, a compulsory license is defined as "allowing a competitor of the patent owner to use the patented invention without the patent owner's permission, and usually for a royalty payment established by the government." See Robert Sherwood, *Intellectual Property and Investment Stimulation: The Ratings of Systems in Eighteen Developing Countries* (1997) 37 IDEA 261.

[162] Frederick Abbott, *The Doha Declaration on the TRIPs Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements*, 2004. Quaker United Nations Office, Occasional Paper 14. Available at <http://www.quno.org>

granted a generic producer/importer, the patent owner will be able to prevent marketing of the equivalent medicine (because it will not consent or acquiesce to marketing). The generic product cannot be put on the market on regulatory grounds, regardless of the grant of license with respect to the patent."[163]

The U.S. is still pressuring developing countries for greater patent protection through threats of trade sanctions and also through the WTO accession process.[164]

2.4 Chapter Summary

At the heart of this chapter is a delineation and discussion of barriers to access to essential medicines. Characterized as 'TRIPs related' and 'Non-TRIPs related', these barriers hinder the effective deployment of cheap essential drugs to needy parts of the world. Next to pharmaceutical patents, which are TRIPs-related, are various bilateral and multilateral agreements initiated by the U.S which have had the most impact on the shortage or lack of important pharmaceuticals in the developing and least developed world. While patents last for a fixed term of twenty years, bilateral and multilateral trade agreements (as with the Supplementary Protection Certificates) negotiated by the U.S introduce stiffer measures which prevent developing countries possessing manufacturing capacity from generically producing off-patent drugs hitherto patented in the U.S.

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[163] *Ibid.*

[164] For instance, Kenya, Malaysia, South Africa, Argentina, the Philippines, India have all received threats of trade sanctions from the U.S. government for their refusal to accommodate its stiffer patent protection for ARVs. India recently bowed to the pressure by enacting the *Patents (Amendment) Act*, 2005. See Oxfam, *Patents versus Patients: Five years after the Doha Declaration*. Oxfam Briefing Paper 95. Online: Oxfam, <http://www.oxfam.org.uk/what-_we_do/issues/health/downloads/bp95_patents.pdf>

These inhibitions, whose principal architects are the U.S and some members of the European Union, have led access advocates to cast a closer look at the recent amendment of the international access mechanism, TRIPs. The following chapter treats this point in detail.

PART III

TRIPS AMENDMENT AS A GLOBAL ACCESS POLICY

3.1 Introduction

Although I have previously argued that some TRIPs-related and non TRIPs-related factors hinder access to affordable medicines in the developing world, it needs be stated that TRIPs contains certain flexibilities designed to foster access to drugs.[165] These flexibilities are compulsory licensing and parallel importing. Though a full discussion of compulsory licensing and parallel importation is not within the purview of my thesis, their impact on access to medicine in developing countries will feature briefly as background to the section on TRIPs amendment. The one that will feature more here is compulsory licensing. A compulsory license, as an alternative to strict enforcement of intellectual property rights, "is one where the government requires that (copy) right owners make their works available to users at a fixed price."[166]

At the inception of TRIPs, western pharmaceutical companies argued that compulsory licensing represented a TRIPs-legitimatized public health option to improve access by increasing the supply of lower cost drugs.[167] One intellectual property law expert sees a liberal system of international compulsory licensing as

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[165] Article 31 of TRIPs provides for compulsory licenses.

[166] S.J. Liebowitz, *Alternative Copyright Systems: The Problems with a Compulsory License,* (Unpublished paper) School of Management, University of Texas at Dallas. Online at <http://www.serci.org/2003/liebowitz2.pdf >

[167] David P. Fidler, *International Law and Public Health: Materials on and Analysis of Global Health Jurisprudence* (New York: Transnational Publishers, Inc., 2000) p. 152.

part of a solution to access problems caused by patent.[168] But the effectiveness of compulsory licensing, as provided for in TRIPs, as an access to drugs tool has always been doubted by developing countries.[169] Particularly contentious is Article 31 (f) that requires that "any such use shall be authorized predominantly for the supply of the domestic market of the member authorizing such use."[170] Because many developing countries lack the manufacturing and financial capabilities needed to fully utilize the potentials of compulsory licenses[171], the "entire compulsory licensing mechanism is rendered practically worthless."[172]

The WTO recognised this concern and in 2001 laid the groundwork for a revision of its strict intellectual property regime with a view to facilitating access to pharmaceutical products to address public health problems affecting developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

Subsequently the WTO declared that:

> We stress the importance we attach to implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines and, in this connection, are adopting a separate declaration.[173]

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[168] See Hutchison, *supra* note 82.

[169] See for instance M.A Oliveira, *et al.*, *Has the Implementation of the TRIPS Agreement in Latin America and the Caribbean produced Intellectual Property Legislation that Favours Public Health?* (2004) 82:11Bull. World Health Org. 815

[170] See Article 31(f) of TRIPs.

[171] See Hutchison; *supra* note 82 at 13, on this point.

[172] See Schechter & Thomas, *supra* note 71 at 399.

[173] Doha WTO Ministerial 2001: *Ministerial Declaration*, Art.17. WT/MIN(01)/DEC/1; Online: http://docsonline.wto.org/DDFDocuments/t/WT/Min01/DEC2.doc (Accessed 22 September 2007). Hereinafter referred to as the Doha Declaration.

The 'separate declaration' is the *Doha Ministerial Declaration on the TRIPS Agreement and Public Health* ('Doha Declaration')[174]

3.2 The Limits of TRIPs Flexibility Defined

The *Doha Declaration* states this:

> We recognise that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement. We instruct the Council on TRIPS to find an expeditious solution to this *problem* and to report to the General Council before the end of 2002.[175] (Emphasis mine)

This paragraph originated from a paper submitted by the European Community to the TRIPs Council special session of pharmaceuticals, in June 2001.[176] In the paper, the European Community suggested that where a country without manufacturing capacity grants a compulsory license, a foreign country could recognise such license and a local manufacturer could be licensed by that foreign country to export the products covered by the patent to the first country.

The 'problem' referred to above is the challenge thrown up by Article 31 (f) of TRIPs; and it has been aptly explained thus:

> Since Article 31 (f) of TRIPs restricts exports of products manufactured under compulsory license, countries without manufacturing capacity dependent on foreign generic producers would have a problem sourcing adequate supplies of generic medicines produced under compulsory license.[177]

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[174] Doha WTO Ministerial 2001: TRIPS; WT/MIN(01)/DEC/2; Online: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (Accessed 22 September 2007).

[175] See Paragraph 6 of the Doha Declaration.

[176] See *Communication from the European Communities and their Member States*, WTO document IP/C/W/280, of June 12, 2001.

[177] Cecilia Oh, *Will the TRIPs Amendment on Compulsory Licensing Work?* (2006) 1 Bridges, pp. 22-23. Available at <http://www.ictsd.org>

In a subsequent paper submitted to the TRIPs Council meeting of March 2002,[178] the European Community put forward two possible approaches for finding the *expeditious solution* sought by paragraph 6 of the Doha Declaration.

The first approach centered on amending TRIPs Article 31 (f) "in order to carve out an exception…for exports of products needed to combat serious public health problems and produced under compulsory licenses."[179] Hutchison suggests an abolition of the entire provision, instead of an amendment.[180] The second approach suggested the interpretation of the 'limited exceptions' phrase in Article 30 in a way that would allow production for export, to certain countries and under certain conditions, of products needed to combat serious public health problems.[181]

For proper understanding, Article 30 of TRIPs provides that: "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

The second approach has been criticized as not compatible with Article 30 above.[182] Carvalho argues that since any exceptions to patent rights must be limited[183], allowing production for export will infract a patent owner's exclusive

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[178] See *Concept Paper Relating to Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health – Communication from the European Communities and their Member States to the TRIPs Council,* WTO document IP/C/W/339, of March 4, 2002.

[179] *Ibid*, para. 16.

[180] Hutchison, *supra* note 82 at 16.

[181] *Supra*, note 178.

[182] Nuno Pires de Carvalho, *The TRIPs Regime of Patent Rights*, 2nd ed., (The Hague: Kluwer Law International, 2005)

[183] Exceptions to the exclusive rights granted to a patent owner are limited. This was the decision reached by the panel in *Canada-Patent Protection pf Pharmaceutical Products*, WT/DS114/R, of 17

rights of preventing others from making, using, offering for sale and selling the patented product under Article 28.1.[184] Moreover, the possibility of granting numerous compulsory licenses in order to meet demands from many developing countries will expand the scope of those licenses, thereby creating unlimited exceptions.[185]

As it will be shown in paragraph 3.4 below, the WTO General Council favoured the first approach. In choosing to amend Article 31 (f) therefore, the WTO General Council expanded the flexibilities under TRIPs in its *Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health* of August 30, 2003.[186] The Council on TRIPs subsequently proposed to the WTO, an amendment of TRIPs that was to draw extensively from the General Council Decision.[187] On the strength of this proposal, the WTO finally amended TRIPs "by inserting Article 31*bis* after Article 31 and inserting the Annex to the TRIPs Agreement after Article 73."[188]

March 2000 and in *United States-Section 110(5) of the US Copyright Act*, WT/DS160/R, of 15 June 2000.

[184] See Carvalho; *supra* note 182, p.332

[185] *Ibid.* Although the second approach was supported by a group of developing countries at the TRIPs Council second special session of June 28, 2002 (see WTO document IP/C/W/355, of June 24, 2002), the US rejected it on the ground that "an interpretation of Article 30 to allow exceptions to patent rights to permit otherwise infringing acts to supply a patented pharmaceutical for purposes of export would seriously prejudice the rights and obligations of Members under the TRIPs Agreement." See *Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health – Communication from the United States*, WTO document IP/C/W/340, of March 14, 2002, at 4; See also, *A Second Communication from the United States of America Relating to Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health*, WTO document IP/C/W/358, of July 9, 2002.

[186] WTO document WT/L/540. Available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm#asterisk ('General Council Decision')

[187] WTO document IP/C/41.

[188] See para. 1 of the *Protocol Amending the TRIPs Agreement,* WT/L/641, 6 December 2005. This Protocol was adopted and submitted to WTO Members for acceptance on December 6, 2005; the Protocol is open for acceptance by Members until 1 December, 2007.

3.3 Pre-Amendment Article 31

Pre-amendment Article 31 of TRIPs had set out twelve conditions that govern the un-authorised use of a patented product without an express or implied consent of the patentee. The conditions, from Article 31 (a) – (l) as explained below limit the flexibilities intended to be introduced by the use of compulsory licenses:

(a) Every un-authorised use will be considered on its own merits

(b) An un-authorised use of a patented product may be permitted provided the user had, prior to the usage, made efforts to negotiate an authorisation on reasonable commercial terms with the patentee which efforts failed to yield results within a reasonable period of time. The un-authorised use may also be permitted in the case of national emergency or other situations of extreme urgency requiring resort to the patented product.

(c) The un-authorised use can only be of a public non-commercial nature:

(d) "The use must be non-exclusive"

(e) An un-authorised user cannot assign the use

(f) The un-authorised use shall only be for the supply of the user's domestic market

(g) The use of the patented product shall be discontinued once the situation that led to the un-authorised usage "ceases to exist or that it is unlikely to recur."

(h) The patentee is entitled to reasonable compensation arising from the economic value of the authorisation

(i) Disputes relating to the legal validity of the authorisation may be settled by a distinct judicial or independent review process in the user's jurisdiction.

(j) Similar to sub-paragraph (i) above, disputes as to reasonable remuneration payable to the patentee may be resolved by a judicial or independent review body in the user's country.

(k) The requirements for evidence of prior negotiations with the right holder before usage and the supply of the domestic market of the user in sub-paragraphs (b) and (f) respectively are not mandatory where the un-authorised usage was to remedy an anti-competitive practice as duly adjudged by a judicial or administrative process.

The most restrictive of these conditions are paragraphs (d), (f) and (g). Under sub-paragraph (d), non-exclusive use means that "where a patent is compulsorily licensed, the patent owner may not be excluded from using its own invention. Nor may it be prevented from licensing the patent to third parties."[189] This will certainly create a commercial problem for the compulsory licensee who may have to face competition from the patentee and third party owners of the patent. Where, therefore, the exploitation of the license involves significant amount of money, the non-exclusive use of the patent may serve as a disincentive to the licensee. In the long run, the need to produce cheap drugs via the grant of a compulsory license may not be served.

The requirement that compulsory licensing of a patented product must be targeted towards predominantly supplying the local market of the Member issuing the compulsory license[190] meant that countries lacking the wherewithal to manufacture the said product could not rely on another country whose government had issued a compulsory license, had the means to locally manufacture the patented

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[189] See Pires de Carvalho, *supra* note 182 at 327

[190] See Article 31 (f) of the TRIPs Agreement.

product and willing to export same to the former. This condition effectively restricted 'compulsory licensing to export markets.'[191] Another commentator asserted that sub-paragraph (f) rendered the entire compulsory licensing mechanism worthless for the WTO members who had no manufacturing capacity- by which he certainly meant developing and least developed countries.[192]

Sub-paragraph (g) limits the lifespan of a compulsory license to a time when the circumstances which led to it "ceases to exist or is unlikely to re-occur." This limited duration of a compulsory will discourage generic producers who are potential licensees since the time frame within which to recoup their investment is unpredictable and entirely dependent on the occurrence or non-occurrence of an event. In a critique of sub-paragraph (g), Morgan has advised that "in any strategy to promote generic production, it is crucial to understand that generic companies, like other business entities, make investments decisions based on future market prospects..."[193]

3.4 Amendment of the TRIPs Article 31[194]

3.4.1 Policy Thrust of Article 31*bis*

Undoubtedly, Article 31*bis* creates a global mechanism for the issuance of compulsory licenses by wealthy nations with the aim of supplying generic versions

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[191] Hutchison, *supra* note 82.
[192] Brook K. Baker, *Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPs Agreement and the Public Health* (2004) 14 Ind. Int'l & Comp. L. Rev. 613.
[193] Maxwell Morgan, *Medicines for the Developing World: Promoting Access and Innovation in the Post-TRIPs Environment* (2006) 64:1 U.T. Fac. L. Rev. 107
[194] WTO document WT/L/641, decision of 6 December 2005.

of patented antiretrovirals to developing and least developed countries with no manufacturing capacity and facing a serious problem of public health.[195]

3.4.2 Description of Article 31*bis*

This dissection of the amendment of the TRIPs Agreement will be carried out having in mind the underlying reason for its introduction, which is to create channels for a better utilization of the access mechanisms in TRIPs. The conscious attempt at eliminating the hurdles inherent in TRIPs Article 31 is couched in the form of the waiver of two provisions of TRIPs Article 31: (a) with respect to the exporting country, a waiver of the "predominantly for the supply of the domestic market of the Member authorizing such use" limitation;[196] and (b) with respect to the importing country, a waiver of the adequate remuneration requirement.[197]

(i) Waiver of the Predominant Domestic Supply Requirement

Paragraph 1 of Article 31*bis* grants that the obligations of an exporting member under Article 31 (f) "shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the production of a pharmaceutical product(s) and its export to an eligible importing member(s) in accordance with the terms set out in paragraph 2 of the annex[198] to the (TRIPs) Agreement."[199] What this simply means is that the predominant domestic supply requirement is waived with

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[195] Frederick M. Abbott & Rudolf V. Van Puymbroeck, *Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision* (Washington, DC: World Bank, 2005) p. 2.

[196] See TRIPs, Article 31 (f).

[197] TRIPs, Article 31(h).

[198] The *Annex* in question is the *Annex to the TRIPs Agreement*, which is actually the new definition section of the amendment of the TRIPs Agreement.

[199] *Supra* note 188.

respect to the compulsory license granted by the exporting country if the conditions set out under paragraph 2 of the annex to the TRIPs Agreement are met.

For the purpose of clarity, it is pertinent to define the principal players in the provision- an "exporting member" and an "eligible importing member". An exporting member "is a member country of the WTO using the system to produce pharmaceutical products for, and export them to, an eligible importing member."[200] An eligible importing member is either a least developed country Member or any Member that has made a notification to the Council for TRIPs of its intention to use the system set out in Article 31*bis* ... as an importer...[201] The definition of an eligible importing member as offered under the amendment will be explored subsequently.

(ii) Conditions for the Waiver of the Predominant Domestic Supply Requirement

The terms to be fulfilled by both the exporting and importing countries before a compulsory license can be issued for drugs to be manufactured and supplied to an eligible importing country are straight forward. One, the eligible importing country has to notify the Council for TRIPs confirming the name and expected quantity of the exact pharmaceutical it seeks to import.[202] Two, the compulsory license issued by the exporting country must contain the exact amount of the pharmaceutical to be produced under the compulsory license, including specific information on labelling and packaging of the pharmaceutical sought to be exported.[203] This requirement for

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[200] Para. 1 (c) of the *Annex to the TRIPs Agreement.*
[201] Para. 1 (b) of the *Annex to the TRIPs Agreement.*
[202] Para. 2 (a) (i), *Annex to the TRIPs Agreement.*
[203] Para. 2 (b) (i) and (ii), *Annex to the TRIPs Agreement.*

specific labelling and packaging is to prevent the diversion of the products into black or unofficial markets where monopoly prices are charged on the legitimate drugs. Lastly, the exporting country shall inform the Council for TRIPs of the grant of a compulsory license and the conditions attached to it.[204]

(iii) Waiver of the Adequate Remuneration Requirement

Article 31 (h) of TRIPs provides that where the patent law of a member nation of the WTO permits it to use a patented product without the authorisation of the patent holder, that member nation shall pay an 'adequate remuneration' to the patent holder, taking into account the economic value of the authorisation. What this means is that the exploitation of a patented product shall attract payment of an 'adequate remuneration' (this should be a sum of money reasonable in the circumstances) which is intended to compensate the patent holder for the breach of his patent right in the product. The TRIPs Amendment has now modified this adequate remuneration requirement thus:

> Where a compulsory licence is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31 (h) shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. *Where a compulsory license is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31 (h) shall not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.*[205] (Italicised to emphasize the addition)

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[204] Para. 2 (c), *Annex to the TRIPs Agreement.*
[205] Para. 2, *Annex to the Protocol Amending the TRIPs Amendment.*

The second sentence of this provision essentially seeks to avoid incidences of double compensation by waiving the obligation to pay adequate remuneration to the pharmaceutical company that produced the needed drugs in the importing country once adequate remuneration had been paid in the exporting country.[206] In other words, when an eligible importing country issues a compulsory license for the production and importation, from an exporting country, of the same antiretroviral for which the former had previously paid adequate remuneration to the latter, there will be no further payment of remuneration to the exporting country, on the strength of paragraph 2 of the TRIPs Amendment.

This provision has yet to be applied by any country since it is novel. A classical illustration would, in a hypothetical sense, be thus: Nigeria had approached Canada for assistance with regard to the use of an antiretroviral produced in Canada. The Nigerian government paid an adequate sum of money as compensation for the compulsory license issued by the Canadian government for that antiretroviral, going by Article 31 (h). But if Nigeria subsequently issued a compulsory license for the same antiretroviral under the TRIPs Amendment, the requirement for Nigeria to adequately remunerate the patent holder is dispensed with.

(iv) Flexible Terms for exporting Pharmaceuticals to Eligible Importing Members

Where a member of the WTO decides, for humanitarian reasons, to export essential medicines to an eligible importing country utilizing the TRIPs Amendment access to drugs mechanism, the exporting country can only embark on this on the

[206] See Abbott & Puymbroeck, *supra* note 195 at 10.

fulfillment of certain terms. From the wordings of the provision, one may describe the requirements as flexible. Paragraph 2 of the *Annex to the TRIPs Agreement* requires that the government of the exporting country:

1. Shall notify the Council for TRIPs of the grant of a compulsory license;[207]

2. Satisfy itself that the importing country has made a notification[208] to the Council for TRIPs that it needs the product. Any notification from an eligible importing country will be made available publicly by the WTO Secretariat through a page on its website;[209]

3. Ensure that the compulsory license it intends to issue states the name and address of the licensee, the product for which the license has been granted, the quantities for which it has been granted, the country to which the product is to be supplied and, the duration of the license.[210]

The TRIPs Amendment also contains provisions encouraging technology transfer and capacity building[211] in and a framework for the assessment of manufacturing capacities in the pharmaceutical sector of developing countries.[212]

This description of the TRIPs Amendment is to provide the background for the analysis of national responses to the Amendment, notably that of Canada, with a view to pointing out the points of divergence between the two access instruments.

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[207] Para. 2 (c) of the *Annex to the TRIPs Agreement.*

[208] TRIPs require eligible importing countries to specify to the WTO, the name and expected quantities of the product needed, to establish its lack of manufacturing capability etc. See Para. 2 (a) & (b) of the *Annex to the TRIPs Agreement.*

[209] See footnote 5 in the *Annex to the TRIPs Agreement.*

[210] *Supra* note 207.

[211] Para. 6 of the *Annex to the TRIPs Agreement.*

[212] *Appendix to the Annex to the TRIPs Agreement..*

This lack of coherence, I argue, presents a challenge to present access to medicines efforts.

3.5 Chapter Summary

Prior to its amendment, intellectual property experts and access advocates criticized Article 31 of TRIPs as unnecessarily restricting the export of drugs to countries with no manufacturing capacity. In amending the TRIPs, the WTO waived, among others, the 'predominant domestic supply' requirement. This was expected to pave the way for an easy flow of generic drugs to impoverished countries. But this has not been the case as will be demonstrated in the following chapter. Chapter three outlines and discusses the salient additions/waiver under the new Article 31*bis*. In the next chapter, a treatment of Canada's efforts to incorporate the new Article 31*bis* into her intellectual property legislation reveals some lacuna. These disconnections are manifested in Canada's restrictive definition of 'pharmaceutical product' and an unhelpful exclusive list of 'eligible importers'. These have combined to limit the ease of access guaranteed by Article 31*bis*.

PART IV

CANADA'S ACCESS TO MEDICINE REGIME

4.1 Introduction

The United Nations, through its Special Envoy on HIV/AIDS in Africa, called on Canada to be the first industrialized nation to employ the TRIPs Amendment in amending its patent law to give poor countries incapacitated by AIDS an affordable source for drugs. In the words of the UN envoy:

> It's time for one of the major industrial countries, in particular, one of the G7 countries, to announce the manufacture and export of generic drugs to Africa. I would wish it to be my country, Canada, but it doesn't really matter which. The proposition is simple: if the World Health Organisation is going to move from 50,000 now in treatment in Africa to over 2 million by 2005 (Africa's share of the 3 million target), then they will need a fast, reliable, scientifically sound, continuous flow of generic drugs in order to keep the prices low enough – roughly $250 to $300 per person per year – for the plan to succeed. There will obviously be some provision from Brazil, Thailand and India but much more will be needed. A western country could fill that need and do it at the highest standards of quality.[213]

At the same time, a broad coalition of aid and development organisations lobbied the Canadian Government to expeditiously implement the TRIPs amendment by amending its intellectual property legislation.[214] The Government of Canada

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[213] Stephen Lewis, *The Politics of Resource Allocation*. Statement by the United Nations Secretary General's Special Envoy on HIV/AIDS at the XIIIth International Conference on AIDS and STIs in Africa (Nairobi, Kenya, 25 September 2003). Online: The Stephen Lewis Foundation, <http://www.stephenlewisfoundation.ca/news_item.cfm?news=1116> (Accessed 2 October, 2007)

[214] Activists like Richard Elliott of the Canadian HIV/AIDS Legal Network and groups such as Students Against Global AIDS and the CAP/AIDS Network Inc. played a key role in coordinating advocacy efforts in Canada under the aegis of the Global Treatment Access Group (GTAG). See Richard Elliott *TRIPS from Doha to Cancun... to Ottawa: Global Developments in Access to Treatment and Canada's Bill C-56* (2003) 8:3 Can. HIV/AIDS Pol'y & L. Rev. pp. 1, 7-18.

proposed changes to its *Patent Act*[215] and the *Food and Drugs Act* as the legal framework of Canada's Access to Medicines Regime ('CAMR')[216] via Bill C-56. Though initially introduced in 2003 as Bill C-56, it was re-titled 'Bill C-9' at the start of a new parliamentary session in 2004.[217] Interestingly, Bill C-9 attracted a glut of criticism[218] from civil society organisations that had advocated tirelessly for it. The most scathing of the criticism centered on fears that certain aspects of the draft Bill varied fundamentally from access guarantees introduced by the General Council Decision[219] and the TRIPs Amendment.

One of the contentious provisions opposed by the Canadian Generic Pharmaceutical Association ('CGPA') in the draft Bill was the 'right of first refusal' accorded brand name producers under the Bill.[220] When faced with the prospect of a generic producer seeking a license to satisfy a sales agreement it had negotiated with an eligible importing country, the patent holder, under a right of first refusal, could decide whether it would fulfill that importing country's order at the price and on the

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[215] R.S.C. 1985, c. P-4.
[216] R.S., 1985, c. F-27.
[217] See, for a complete chronicle of events leading to its passage, Elliott, *supra* note 214.
[218] Most of the issues are well documented in the submission made by the Canadian HIV/AIDS Legal Network to the committee during its public hearing. See especially, Canadian HIV/AIDS Legal Network, *Global Access to Medicines: Will Canada Meet the Challenge? A submission to the Standing Committee on Industry, Science and Technology regarding Bill C-9, An Act to amend the Patent Act and the Food and Drugs Act* (26 February, 2004). Online: AIDSlaw, <http://www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=1040> See also Canadian HIV/AIDS Legal Network, *Global Access to Medicines: Will Canada Meet the Challenge? Supplementary Submission to the Standing Committee on Industry, Science and Technology regarding Bill C-9, An Act to amend the Patent Act and the Food and Drugs Act* (8 March, 2004). The latter submission specifically addressed the issue of 'right of refusal' which Bill C-9 initially granted brand-name producers in Canada. (Both were accessed 5 October, 2007).
[219] *Supra* note 185.
[220] Canadian Generic Pharmaceutical Association, *Generic Industry Welcomes Introduction of Access to Generic Medicines Bill, Details of Full Legal and Regulatory Package will Determine Practical Effect,* News Release, 6 November, 2003. Online: CGPA, <http://www.canadiangenerics.ca/en/news/nov_06_03.shtml> (Accessed 6 December, 2007).

conditions that country had arranged with the generic supplier.[221] That is simply supplanting the generic producer who had negotiated the transaction.

This prompted the CGPA to warn that "if Generic pharmaceutical manufacturers spend time and money arranging the details of an agreement only to have the brand company that holds the patent take over that agreement, they will quickly realize the futility of trying to make the agreement work."[222]

The Bill was eventually passed in May 2004 as the *Jean Chrétien Pledge to Africa Act* ('JCPA').[223] And in the words of Paul Martin, Canada's then Prime Minister: "Canada was the first country to respond to the call for international assistance, and this legislation has been hailed as a model to the world."[224] Since its passage, the legislation has only been used to export essential drugs to an African country (Rwanda) once.[225]

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[221] *Ibid.*

[222] *Ibid.*

[223] Its official title is *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)* R.S.C. 2004, c.23. Curiously, the sub nom, *Jean Chrétien Pledge to Africa*, created some discontent within the opposition parties. According to Prof. Mathew Rimmer in an essay on the Act, James Rajotte of the Conservatives criticized the precedent of naming a legislation after a politician. In his words, "It is a pledge largely to the epidemic in sub-Saharan Africa, that is true, but there are many other nations in the developing world that are on the lists of for good reason and we should not exclude them from the title and intent of the Bill." To Dick Proctor of the New Democratic Party, the Bill should appropriately bear the name of Stephen Lewis: "It was Stephen Lewis who brought this to the attention of Canadians and, indeed, people around the world and it is important that it be recognised at this time." See Matthew Rimmer, *The Jean Chrétien Pledge to Africa Act: Patent Law and Humanitarian Aid* (2005) 15:7 Expert Opin. Ther. Patents 889-909 at 892.

[224] Paul Martin, *Prime Minister's Statement on Amendments to Bill C-9: The Jean Chrétien Pledge to Africa Act.* Ottawa, Ontario. 20 April, 2004. Online: Government of Canada, <http://www.pm.gc.ca/eng/news.asp?category=3&id=180>

[225] See Unnati Gandhi, *Canadian First for AIDS Drug*, in the *Globe and Mail* (6 October 2007) p. A21. Online: <http://www.theglobeandmail.com/servlet/ArticleNews/freeheadlines/LAC/20071006/international/International> (Accessed 11 October 2007)

4.2 The Policy direction of Canada's Access to Medicines Regime

The objective behind the introduction of Canada's Access to Medicines Regime (CAMR) is succinctly stated as follows:

> Canada's Access to Medicines Regime provides a way for the world's developing and least-developed countries to import high-quality drugs and medical devices at a lower cost to treat the diseases that bring sufferings to their citizens. It is one part of the Government of Canada's broader strategy to assist countries in their struggle against HIV/AIDS, tuberculosis, malaria and other diseases."[226]

This strategic policy is reiterated in the summary section of the JCPA thus:

> This enactment amends the Patent Act and the Food and Drugs Act to facilitate access to pharmaceutical products to address public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.[227]

Any effort to critically dissect an enactment directed, principally, at removing bottlenecks to global access to affordable medicines must, arguably, proceed from the WTO perspective on the public health- intellectual property rights discourse. That is, intellectual property rules must be construed in a sense to provide solutions to global public health issues. The WTO expressly affirmed this in the Doha Declaration:

> We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to promote public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, *we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO*

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[226] See Government of Canada, *Canada's Access to Medicines Regime.* Online: <http://camr-rcam.hc-sc.gc.ca/index_e.html> (Accessed 6 October 2007).

[227] See *Summary* of the JCPA, *supra* note 219. The *Patent Act* (as amended) captions the new section 21 as "Use of Patents for International Humanitarian Purposes to Address Public Health Problems."

Members' right to protect public health and, in particular, to promote access to medicines for all.[228] (Italicised for emphasis)

Accordingly, the *JCPA* should wholly accommodate the flexibilities introduced by the TRIPs Amendment. In this context, the *JCPA* and all similar enactments must seek to strengthen the access mechanisms enabled by the TRIPs Agreement.

The following analysis of the JCPA does not aim at discountenancing the lofty public health intentions of the Canadian Government but will attempt to point out its disconnection from the General Council Decision and the TRIPs Amendment, in respect of the stated purpose of Canada's foremost access to drugs initiative. This analysis may well provide useful insights into the difficulties encountered by key players in Canada's generic pharmaceutical industry and non-governmental organisations when trying to utilise the JCPA to provide essential drugs to the needy.

4.3 THE JCPA AND ITS DISCONNECTION FROM TRIPS AMENDMENT

4.3.1 Exportable Pharmaceutical Products

The JCPA defines pharmaceutical products as "any patented product listed in Schedule 1 in, if applicable, the dosage form, the strength and route of administration specified in that Schedule in relation to the product."[229] Schedule 1 to the JCPA provides a list of fifty-six drugs and medical devices that can be produced by generic companies upon the issuance of a compulsory license by Canada's Commissioner of Patents. The Governor in Council is empowered to amend the list of pharmaceutical

[228] Para 4 of the Doha Declaration, *supra* note 173.
[229] S.21.02, *Patent Act,* R.S., c. P-4

products by an order on the recommendation of the Minister of Health by the addition of a patented product that could be used to combat public health problems in developing and least developed countries.[230]

Access activists contend that as part of the negotiations leading up to the General Council Decision and subsequently the TRIPs Amendment, all WTO members had agreed that there would be no limit to the number of patented pharmaceutical products available for generic production and exportation to eligible importing countries.[231]

The CGPA's position is that there should be no limit on eligible pharmaceutical products because the governing international access instrument, that is the TRIPs Amendment, did not require any limit.[232] Section 21.02[233] of the *Patent Act* runs counter to the wide definition of pharmaceutical products in the TRIPs Amendment:[234]

> Pharmaceutical Product means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognised in paragraph 1 of the Declaration on the TRIPs Agreement and Public Health (WT/MIN/(01)/DEC/2). It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included.

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[230] S. 21.03 (1) (a) (i), *Patent Act,* R.S., c. P-4

[231] Richard Elliott, *Pledges and Pitfalls: Canada's Legislation on Compulsory Licensing of Pharmaceuticals for Export* (2006) 1:1/2 Int. J. Intellectual Prop. Management 101.

[232] See CGPA, *supra* note 220 at 4.

[233] Section 21.02 reads thus: " 'pharmaceutical product' means any patented product listed in Schedule 1 in, if applicable, the dosage form, the strength and the route of administration specified in that Schedule in relation to the product." However, Schedule 1 to the JCPA contains a list of fifty-six drugs and medical devices, thereby excluding diagnostic kits and other drugs that could be used in the treatment of HIV/AIDS, malaria, tuberculosis and other diseases.

[234] Para.1 (a), *Annex to the TRIPs Agreement.*

Also missing from the JCPA's definition of pharmaceutical products are active ingredients necessary for the manufacture of drugs and the diagnostic kits for its use. These are part of pharmaceutical products as defined under TRIPs Amendment reproduced above. The definition of pharmaceutical products in the JCPA that specifies certain eligible drugs remains one of the points of departure from TRIPs Amendment that governs the access to medicines intervention at the international level.

4.3.2 Eligible Importers

Under section 21.04 (1), the JCPA permits the Commissioner of Patents to grant a compulsory license to a person who has applied for and paid the prescribed fee for a compulsory license. The contents of the application for a license are specified under section 21.2 (a)-(g). Of note, however, is paragraph (f) which provides that one required piece of information is: "…the name of the governmental person or entity, or the person or entity permitted by the government of the importing country, to which the product is to be sold, and prescribed information, if any, concerning that person or entity…"

The CGPA argues that '…or the person or entity *permitted* by the government of the importing country…' is partly responsible for the inability of generic manufacturers and non-governmental organisations to utilise the JCPA.[235] The use of the word 'permitted' requires that NGOs like the Treatment Action Campaign (TAC) of South Africa must first obtain the express consent of the South

[235] See CGPA, *supra* note 220.

African government before Canadian authorities will allow export of medicines to South Africa on the request of TAC.

Article 31*bis* does not reduce the chances of a non-governmental agency to import generics to an impoverished country to the government of that country's permission. Its inclusion in the JCPA expressly excludes non-governmental organisations from participating in the process.

4.3.3 Conditions for the Grant of Compulsory Licenses

The most convoluted of the procedures under the JCPA is that of the grant of compulsory license. The JCPA spells out a series of conditions that an applicant for a compulsory license is expected to comply with before the Commissioner of Patents issues a license. The conditions are as follows:

1. A drug produced under authorisation in Canada for export to another country must not only be marked, packaged, labelled and embossed in line with the requirement of the WTO; the licensee must also seek the approval of the patentee with respect to the manner of packaging, labeling, marking and embossment adopted by the licensee.[236]

The condition to seek marking, labelling, packaging and embossing approval from the patent holder is not required under the TRIPs Agreement and the General Council Decision.[237] By requiring an approval from the holder of the patent on the drug meant for export, the JCPA makes it easy for brand name producers to delay the process for license application.

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[236] Section 21.04 (3) (b) (ii) of the *Patent Act*.
[237] See Para. 2 (b) (ii) of the *Annex to the TRIPs Agreement*.

2. The JCPA also requires an applicant for a compulsory license to provide a certified copy of the notification an eligible importing country has made to the Council for TRIPs specifying the name and quantity of the pharmaceutical product sought to be imported as required of an eligible importing country under paragraph 1 (a) of the General Council Decision and also Paragraph 2 (a) of the *Annex to the TRIPs Agreement*.

The point of disconnection here is that the TRIPs Amendment is less onerous than the JCPA being that the former makes it clear that any notification from an eligible importing country will be posted on its website from which it expects the government of the exporting country to confirm.[238]

3. An applicant for a license is expected, under the JCPA, to make separate applications for every patented invention to which his application relates.[239] According to the CGPA, this is rather difficult requirement to fulfill because patentees usually assert that there are dozens or hundreds of patents owned by many patentees to which a single application for a compulsory license relates.[240]

In a situation where some diagnostic kits (these are not currently included in JCPA's definition of pharmaceutical product) are related to a pharmaceutical product, an applicant for a license is expected to apply separately for the production and export of the diagnostic kits. This relates to the advertent exclusion of diagnostic kits and active ingredients from the JCPA's definition of pharmaceutical products.[241] Under the TRIPs Amendment, diagnostic kits are considered part of a

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[238] See note 209 for more explanations.
[239] S.21.04 (2) (d) of the *Patent Act*.
[240] See CGPA, *supra* note 220.
[241] See note 229, *supra*.

pharmaceutical product thus requiring a single application.[242] The confusion created causes undue delay in sorting out which patented invention relates to a particular application for a license.

4. The life of span of a compulsory license granted by the Commissioner of Patents is fixed at two years,[243] subject to one renewal of not more than two years[244] on a sworn certification by applicant for a renewal that the quantities of a pharmaceutical product for which the license was initially issued had not been exported before the license ceased to be valid.[245]

There is nothing in TRIPs or Article 31*bis* that restricts the validity of a compulsory license under the WTO system to a certain number of years. Although article 31 (c) of TRIPs provides that "the scope and duration of the use shall be limited to the purpose to which it was authorised", it clearly does not limit the lifespan of a compulsory license issued under TRIPs to specific number of years. It is quite likely that the essential drugs exported for humanitarian purposes may still be needed by the eligible importing country after the expiration of the license. This would mean that the whole intricate process of applying for a license would have to be undertaken all over if the public health problem persists.

4.3.4 Patentees' extra Litigation Rights

A brand name pharmaceutical company has three distinct rights to commence judicial actions against a generic company-applicant during the process of applying

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[242] See para. 1 (a) of the *Annex to the TRIPs Agreement* for the definition of 'pharmaceutical product' under the TRIPs Amendment. *Supra* note 234.
[243] S.21.09 of the *Patent Act*.
[244] S.21.12 (2) of the *Patent Act*.
[245] S.21.12 (1) of the *Patent Act*.

for or after the grant of a license. One, a patentee is empowered to seek, from the Federal Court, an order providing for the payment of a royalty that is greater than the royalty that ought to be paid in accordance with the TRIPs Amendment.[246]

Another of the rights enables a patentee to apply for an order, from the Federal Court, terminating an agreement concluded between a licensee and an eligible importing country on specified grounds.[247] Some of the grounds upon which an order of termination may be based, under this section, create room for manipulation and delay of the system by a patentee. For example, the patentee may claim that the information supplied by the applicant to the Commissioner of Patents is inaccurate[248], or that he has failed to upload similar information to a website he is required to operate;[249] or that the product exported to the eligible importing country has been re-exported, with the applicant's knowledge, to another country.[250]

In addition to the aforementioned rights, a patentee may apply to the Federal Court for an order terminating an agreement on the ground that it is commercial in nature.[251] Any agreement reached between a generic company and an eligible importing country that is commercial in nature is contrary to the declared objective of CAMR, which is to facilitate access to cheap drugs for poor patients on a humanitarian basis.[252] The Federal Court can terminate the agreement or order the payment of an additional royalty to the patentee if it is proved that the average price

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[246] S. 21.08 (4) of the *Patent Act*.
[247] S. 21.14 of the *Patent Act*.
[248] S. 21. 14 (a)
[249] S. 21.14 (b)
[250] S.21.14 (f). Note that under the TRIPs Amendment, a member of a regional trade agreement may bulk purchase pharmaceutical products and re-export to other members of the regional trade agreement suffering similar public health problem.
[251] S. 21.17 (1) of the *Patent Act*.
[252] *Supra* note 226.

of the product to be manufactured under the license is equal to or greater than twenty five percent of the average price in Canada of the equivalent product sold by or with the consent of the patentee.[253] This, it is believed, is to prevent generic companies from taking economic advantage of the plight of the patients in the eligible importing country.

The CGPA argues that existing general remedies in the Patent Act[254], prior to its amendment by the JCPA, provide adequate legal channels for a patentee to challenge a generic manufacturer where the latter is in breach of the conditions of a license.[255]

4.4 Novel Provisions in the JCPA

Aside from the inconsistencies evident in the analysis of the JCPA and the TRIPs Amendment, the JCPA has introduced some notable flexibilities which are meant to diffuse the tension that exist between generic and brand name pharmaceutical manufacturers in the access to medicines scheme.

4.4.1 Time Frame for Negotiating a Voluntary License

Under Article 31 (b) of TRIPs, before a compulsory license is issued, the applicant for a compulsory license must first make efforts to obtain authorisation from the patentee on reasonable commercial terms and conditions. In the event that negotiations between the applicant and the patentee fail "within a reasonable period of time", a compulsory license may then be issued by the relevant authority to the

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[253] *Supra* note 246.
[254] Sections 53 and 54 of the *Patent Act* deal with remedies for the infringement of a patent.
[255] See the CGPA, *supra* note 220 at 3.

applicant.[256] The requirement for authorisation by a patentee before the grant of a compulsory license is excused where there is a "national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.[257]

Prior to the promulgation of the JCPA, issues were raised about the lack of certainty as to what constitutes a "reasonable period of time" and "reasonable commercial terms and conditions" when negotiating a voluntary license.[258] One particular fear was that in a heavily litigious pharmaceutical sector, a patentee with considerable financial muscle may argue that a generic company's abandonment of negotiations was unreasonably premature or that the generic company was unwilling to accept the patentee's 'reasonable terms and conditions.'[259] Unfortunately, both the General Council Decision and the TRIPs Amendment omitted any clarification of the two phrases.

Canada has now offered some statutory clarity to the two phrases. 'Reasonable commercial terms and conditions' or 'royalty' is defined in section 8 (3) of the JCPA's *Use of Patented Products for International Humanitarian Purposes Regulations*.[260] The section sets out a formula for calculating what the royalty payable to a patentee in a given case shall be, based on the ranking of the eligible importing country on the Human Development Index of the United Nations Development Programme.[261]

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[256] TRIPs, Article 31 (b).
[257] *Ibid.*
[258] See Elliott, *supra* note 231 at 99.
[259] *Ibid.*
[260] S.O.R. 2005/143. Available at Canada Gazette, <http://canadagazette.gc.ca/partII/2005/20050601/pdf/g2-13911.pdf>
[261] *Ibid.* See S. 8 (3)- (6).

Where negotiations for a voluntary license continue for an unreasonable length of time or a patentee is unwilling to accept the statutorily declared royalty, a generic producer shall observe a thirty day period before a compulsory license is granted by the Commissioner of Patents.[262]

4.4.2 Utilisation by Non-WTO Members

Whereas the access to drugs mechanisms in the General Council Decision and the TRIPs Amendment can only be employed by WTO members, whether developed, developing or least-developed, the JCPA took a step further by championing the cause of poor patients in developing and least-developed countries that are not members of the WTO. Interestingly, the JCPA permits export of pharmaceutical products to countries that are not members of the WTO.

A developing country that is neither a member of the WTO nor a least – developed country can procure pharmaceutical products from Canadian generic producers, using the JCPA, if it is eligible for official development assistance according to the Organisation for Economic Cooperation and Development (OECD)[263] and states in a notice to the Government of Canada:

(i) that it is faced with national emergency or other circumstances of extreme urgency,[264]

(ii) the name and quantity of the pharmaceutical product needed to combat the emergency or other urgency,[265]

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[262] S.21.04 (3) (c) (i) of the *Patent Act.*
[263] S.21.03 (1) (d) (ii) of the *Patent Act.*
[264] S. 21.03 (1) (d) (ii) (A) of the *Patent Act*
[265] S. 21.03 (1) (d) (ii) (B) of the *Patent Act.*

(iii) that it has no, or insufficient, pharmaceutical capacity to manufacture that product and,[266]

(iv) that it agrees that the product will not be used for commercial purpose and that it is ready to take reasonable measures to prevent re-exportation of the products.[267]

In spite of these laudable provisions, criticism of the *JCPA* and its failure to deliver on its objective are still growing. Prof. Attaran, on his part, has suggested that two competing theories may be responsible: the first is the JCPA's complexity.

> The law stipulates that charities and governments in poor countries, working with Canadian manufacturers of generic drugs, may apply to Canada's Commissioner of Patents for a 'compulsory licence'- a type of patent override. But applications must be filed and processed singly; they cannot be shared by countries or charities who want to band together to submit joint applications to minimize the work of the application process.[268]

Using the second theory, the JCPA's irrelevancy, he argues (and rather incorrectly)[269] that of the 319 products termed 'essential medicines' by the WHO, only 17 were patented in 65 developing countries surveyed so that overall the patent incidence was just 1.4%.[270]

Although he recommends the JCPA to other developed nations, Richard Elliott puts the defects in the law down to a two-fold issue: one is that the *JCPA* failed to incorporate the 'flexibilities' allowed under WTO law (which I have

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[266] S. 21.03 (1) (d) (ii) (C) of the *Patent Act*.
[267] S. 21.03 (1) (d) (ii) (D) of the *Patent Act*.
[268] Amir Attaran, *A Tragically Naïve Canadian Law for Tragically Neglected Global Health* (2007) 176:12 CMAJ 1726; See also Elliott, *supra* note 231.
[269] In Part II of this paper, I had argued against this assertion on the basis of results of studies which revealed that though the incidence of patenting is generally low in third world countries, however the few patented antiretrovirals are the most efficacious in resource-poor settings in developing and least-developed nations.
[270] See Attaran, *supra* note 98 at 66.

demonstrated); and two, that the law contains some TRIPS-plus features that undermine its functionality.[271]

4.5 Chapter Summary

In amending Article 31 of TRIPs, the WTO implored its member-nations to either enact (where none previously exists) or amend their domestic intellectual property statute to conform with the specific objective of supplying essential drugs to developing and least developed countries most affected by the scourges of HIV/AIDS, malaria and tuberculosis. Canada pioneered compliance with the WTO directive. This chapter therefore dissects the *Jean Chretien Pledge to Africa Act* ('JCPA'). This is the legal instrument for Canada's Access to Medicines Regime ('CAMR').

The JCPA disconnects from the TRIPs Amendment in some material particulars. These disconnections, I have argued as my thesis, are indicative of the single usage of the JCPA to export drugs to a developing country since 2004, the year of its passage. Though the JCPA is generally more restrictive as an implementing legislation for the TRIPs amendment, it however provides some measures which are better, from an access perspective, than what the TRIPs amendment provides. This is apparent in its definition of 'reasonable time and conditions' and the extension of the access mechanism to non-WTO members of the OECD.

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[271] Elliott, *supra* note 231 at 109.

PART V

CONCLUSION

Though the *JCPA* is a timely response to the call for international assistance in creating access to essential but affordable medicines, it nevertheless exhibits- in its current form- lack of a clear-cut mandate to foster a radical change to the desperate global public health crisis. It is thought that Canada's overriding commitment to its multilateral trade agreement negotiated with the U.S and Mexico played more than a fleeting role in incapacitating the *JCPA* as a model access mechanism.[272]

The call for alternative incentive schemes for access to essential pharmaceuticals is hinged on the reasoning that intellectual property rights have failed to provide the hugely anticipated incentive.[273] Patents have not led to- and are not likely to lead to- the development of new medicines.[274] This assertion supports the case for a change. The following focuses on other options capable of resolving the intellectual property rights- access to medicines tension.

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[272] Both Canada and the U.S had been quick to counter this assertion. In July 2004, the US and Canada adopted a Memorandum of Understanding agreeing that the intellectual property provisions of the North American Free Trade Agreement (NAFTA) would not be applied so as to block the implementation of Canada's Bill C-9. See Letter from Robert Zoellick to Hon. James Peterson, then Canada's Minister for International Trade- 16 July, 2004. Online: Office of the Trade Representative, <http://www.ustr.gov/assets/Trade_Sectors/Intellectual_Property/asset_upload_file426_6319.pdf>

[273] Michael J. Selgelid & Eline M. Sepers, "Patents, Profits, and the Price of Pills: Implications for Access and Availability" in Jillian Clare Cohen *et al*, eds., *The Power of Pills: Social, Ethical and Legal Issues in Drug Development, Marketing, and Pricing* (London: Pluto Press, 2006) at 159.

[274] *Ibid.*

5.1 Emerging Access Paradigms

The key to finding a workable solution lies in fairly balancing drug manufacturers' interest in investing in mainly profitable pharmaceutical research[275] and the availability of affordable drugs for the sick in developing countries. Experts in the field have put forward a host of ideas on this subject, which I outline subsequently. This move notwithstanding, deciding on which option(s) best suit the present situation has been made the more difficult by their omission from the agenda of local and international discourse on public health issues. Patent right as an incentive to innovate is now a readily drawn-on resource for the drug industry when matters of affordable access to its products arise. Any alternative incentive scheme must therefore reconcile competing demands for drugs and patents as incentive to innovate in order to be feasible and also make a meaningful impact.

Since the current measures under TRIPS- compulsory licensing in particular- has proved inadequate to meet the ever-increasing demand for cheap medications in developing countries, and pharmaceutical companies are unyielding in their argument for patent protection for pharmaceutical products, recourse to agreeable option(s) becomes a necessity.

5.2 Alternative Incentive Schemes

Certain models currently compete for prominence in the pharmaceutical incentive-to-innovate arena. These are:

1. Financial Incentive Programmes

2. The Proportional Reward System

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[275] See Morgan, *supra* note 193.

3. Competitive intermediaries, and the

4. Medical Innovation Prize Fund

5.2.1 Financial Incentive Programmes

The plank of this idea is that wealthy donor organisations or countries should offer advance guarantees to pharmaceutical companies that they will be financially rewarded for developing and delivering the kind of technologies most needed from a global health perspective.[276] For a start, research and development (R&D) system in high-income countries involves a combination of push and pull techniques. According to a seminal text on financial incentives for medical research into global diseases, government organisations such as the US National Institute for Health (NIH) support basic research through the 'push' technique while the private (pharmaceutical) sector is enticed to turn these into usable outcomes by the promise of a patent-protected market (the 'pull' technique).[277]

Applying this concept to production of vaccines and drugs for developing countries suggests using the *push* programme for basic research and the *pull* programme to encourage biotech and pharmaceutical firms to turn this research into vaccines and drugs. It is well established by now that pharmaceutical companies' governing incentive for investing in R&D is the prospect of future sales.[278] Consequently, Kremer and Glennerster have distinguished between the 'Push' and 'Pull' approaches.

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[276] *Supra* note 273.

[277] Michael Kramer & Rachel Glennerster, *Strong Medicine: Creating Incentives for Pharmaceutical Research on Neglected Diseases* (Princeton, New Jersey: Princeton University Press, 2004)

[278] *Ibid.*

1. **Push Technique**

The push programme, according to Kremer and Glennerster, subsidizes research inputs through means such as grants to academics, public equity investments in product development, tax credits for R&D investment, and outlays for government laboratories. A major problem identified with this approach is that in grant-financed research, advocates for particular diseases and scientists working on these diseases have an interest in portraying research opportunities favourably.[279]

Decision makers, in Kremer and Glennerster's opinion, are thus likely to find it very difficult to assess the scientific opportunities for research on HIV/AIDS, malaria and tuberculosis vaccines and drugs. They may end up financing ideas with only a small prospect of success- or worse, failing to fund promising research because they do not have the confidence in the objectivity of its backers.

2. **Pull Technique**

A pull programme, in contrast to the push programme, increases the rewards for developing specific products by committing to reward success- for example, by guaranteeing to purchase a certain quantity and/or agreeing to pay at least a minimum price for the product. This is also known as an 'Advance Purchase Commitment'.[280] The distinction is mainly between paying for research inputs and paying for research outputs. With respect to enticing pharmaceutical firms to

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[279] *Ibid.*

[280] Michael Kremer, *Public Policies to Stimulate Development of Vaccines and Drugs for the Neglected Disease* in Commission on Macroeconomics and Health Working Paper Series (Geneva: WHO, 2001) Paper No. WG2:8 at 12. Online at <http://www.cmhealth.org/docs/ wg2_paper8.pdf>.

produce affordable drugs and vaccines for HIV/AIDS, donor organisations and national governments should, by employing the pull programme:

> Commit (legally, via public offering) in advance to purchasing specified numbers of things like malaria vaccines (meeting predetermined specifications) at specified prices from the companies that develop them. If such advance commitments were sufficiently attractive, reflecting the true social value of the technologies in question, then pharmaceutical companies would have an (otherwise lacking) incentive to develop medical technologies most needed in developing countries. Because the purchase and provision of the vaccine, drug, or other technology would be assured in advance, and because stipulations would be made about price (i.e., that after X doses are sold at price Y, the company must provide additional doses at reduced price Z) concerns about *availability* as well as *access* to essential medicines are accounted for.[281]

The financial incentive approach suggests no alternative to patent protection for the vaccines, drugs and other technologies. In this light, pharmaceutical companies will still have their domineering say. Similarly, since national governments and donor organisations are to negotiate with the companies; and considering the feeble economic state of affected developing nations, pharmaceutical companies are more likely to proceed to the deliberations as stronger parties than the afflicted countries.

Although the 'pull technique' will be more attractive to pharmaceutical companies, some initiatives to promote research into neglected diseases have been championed through the 'push' technique.[282] The International AIDS Vaccine

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[281] *Supra,* note 273.
[282] *Supra note* 275 at 102

Initiative (IAVI), using the push technique, recently called on the Group of Eight Nations (G8) to establish a multi-billion dollar fund for AIDS vaccines.[283]

5.2.2 Proportional Reward System

This programme, conceived by Thomas Pogge[284], has two components. The first envisages the possibility for any drug manufacturer to use any products coming from the successful research efforts of other firms (including manufacturing details, results of clinical testing, and regulatory approval data) "free of charge". Going by Pogge's postulation, the resultant increase in competition would bring down prices close to their manufacturing cost, thereby making the drugs as affordable as possible. However, to ensure future pharmaceutical research, drug companies will need to be rewarded for engaging in innovative research.[285]

As a means of stimulating this, the second component of the Pogge's *public-good strategy* suggests that:

> Inventor firms should be entitled to take out a multiyear patent on any essential medicines they invent but, during the life of the patent, should be rewarded, out of public funds, in proportion to the impact of their invention on the global disease burden. This reform component would reorient the incentives of such firms in highly desirable ways: Any inventor firm would have incentives to sell its innovate treatment cheaply (often even below their marginal cost of production) in order to help get its drugs to even very poor people who need them.[286]

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[283] International AIDS Vaccine Initiative, *Strengthening the G8 Commitment to AIDS Vaccines: Concrete Steps to Accelerate AIDS Research and Delivery, Proposals from the International AIDS Vaccine Initiative*, 2005. Online: <http://www.g8.utoronto.ca/speakers/g8outreach2005/iavi_g8_long.doc>

[284] Thomas W. Pogge, "Human Rights and Global Health: A Research Program" (2005) 36:1/2 Metaphilosophy 182-209.

[285] *Ibid.*

[286] *Ibid* at 188-189.

The tradeoff here is that the more successful a drug is in reducing the global mortality and morbidity caused by a particular disease, the higher will be the financial reward- and thus incentive- for the inventor. Pogge's main point is that essential drugs should be seen as global public goods and their development should thus be paid for out of public funds in proportion to their true public value- that is, the extent to which they reduce morbidity and mortality. Simply put, the financial reward for an inventor should be inversely proportional to the level of decrease of a particular disease its medical invention brings about. Some experts however observe that the *public-good strategy* complements rather than substitute the current patent regime.[287]

5.2.3 Competitive Intermediaries

Hubbard and Love[288] have proposed- as part of an open source developmental model- a system whereby 'competitive intermediators' will invest in R&D projects on behalf of employers. Under this proposal, employers would be required to contribute to entities that fund medical R&D; and the employer would choose which R&D fund manages its money.[289] What is unclear in this model is the definition of 'employers' and 'intermediators' and their exact roles in the scheme since the propounders of the idea did not provide any suggestions. If the 'employers' are the producers and 'intermediaries/intermediators' are the marketers, advertisers

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[287] See Selgelid & Sepers, *supra* note 273 at 160.

[288] James Love and Tim Hubbard, *Paying for Public Goods* in Rishab Aiyer Ghosh, ed., *CODE: Collaborative Ownership and the Digital Economy* (Cambridge, Mass.: MIT Press, 2005)

[289] James Love, "Measures to Enhance Access to Medical Technologies, and New Methods of Stimulating Medical R & D" (2006-2007) 40 U.C. Davies L. Rev. 679

and middlemen in typical economic models, the "competitive intermediators" system would come across as new only in name.

It is even somewhat unlikely that this scheme would receive wide acceptance given that some commentators[290] posit that the failure to create access to essential medicines in poor nations is, in essence, down to a market failure. Economists typically hold intermediaries- or middlemen- are being responsible for the increase in the prices of goods and services from the point the products depart the manufacturers' stable. To advance an alternative that is intrinsically hinged on intermediaries- like marketers and advertisers- is a circuitous and non problem-solving measure.

5.2.4 Medical Innovation Prize Fund

Under the Medical Innovation Prize Fund (MIPF) system, national governments are to set aside a fixed amount of money (a percentage of their Gross Domestic Product[291], for instance) and award this money to medical innovators on the basis of the demonstrated value of their products.[292] This practice could increase the amount of funding available to R&D while reducing the cost of pharmaceuticals to the end users.[293]

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[290] See particularly Selgelid and Sepers, *supra* note 273 at p.159.

[291] In the U.S., it will be .5% (fifty basis points) of U.S. GDP. See note 279 at p.700. See also James Love, *Drug Development Incentives to Improve Access to Essential Medicines* (2006) 84:5 Bull. of the W.H.O 408.

[292] James Love, *Remuneration Guidelines for Non-voluntary Use of Patent on Medical Technologies*, Health Economics and Drugs, TCM Series No. 18 (2005) Online: WHO, http://www.who.int/medicines/areas/technical_cooperation/WHOTCM2005.1_OMS.pdf (Accessed 28 October, 2007)

[293] *Ibid.*

The US is in the process of legislating on this approach via the *Medical Innovation Prize Act.*[294] The legislation seeks to provide generic producers non-voluntary authorisations to use any and all patents (and *Sui generis* intellectual property rights, such as rights in registration data) relevant to the manufacture and sale of all prescription medicines in the U.S market. The sponsor of the Bill projects that:

> Rather than rely on high drug prices as incentive for R&D, the Bill would directly reward developers of medicines, on the basis of the incremental therapeutic benefit to consumers, through a new Medical Innovation Prize Fund. Prices for prescription drugs to consumers would be at low generic prices immediately upon entry to the market. By breaking the link between drug prices and R&D, it would provide more equitable access to medicine, end rationing and restrictive formularies, and manage overall R&D incentives through a separate mechanism that can be increased or decreased, depending on society's willingness to pay for medical R&D.[295]

In addition, minimum level of funding would be established for priority health care needs, including global infectious diseases that qualify under the U.S. *Orphan Drug Act*[296], and neglected diseases primarily affecting the poor in developing countries.

Once operational, the remuneration will be paid directly to the innovator regardless of which firm actually sells a product (medicines) to consumers. Different innovators with new drugs will compete against each other, and the prize would be awarded for the first ten years a pharmaceutical is in the market, based on the incremental health benefits of the drug when compared to existing medicines.[297]

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[294] U.S., Bill, H.R. 417, 109th Cong., 2005. The Bill was introduced by Rep. Bernard Sanders in January 2005.

[295] National Institutes of Health: Office of Legislative Policy and Analysis, *Medical Innovation Prize Act of 2005*. Online: OLPA, <http://olpa.od.nih.gov/legislation/109/pendinglegislation/medicalinnovation.asp> (Accessed 28 October 2007)

[296] Pub. L. 97-414.

[297] *Supra*, note 289 at 701.

5.3 Recommendation on JCPA as an Access Model

The clear areas of incoherence between the JCPA and the TRIPs Amendment require amendment of the JCPA in order to bring it in with the WTO's objective of interpreting intellectual property legislation to promote public health measures. But the JCPA cannot be said to be short of public health promotion measures. At the least, it is laudable that the JCPA emphasizes a humanitarian perspective to solving the access to medicines problem.

In amending the JCPA to better serve its purpose, the Government of Canada must take an active role in negotiating access to Canadian generics so as to clearly reflect its altruistic intention to aid severely diseased regions of the world. As it is presently, the JCPA merely creates a platform for private parties- that is licensees and patentees- to haggle over particulars of a license. The government bears no significant financial responsibility and stimulates no negotiation between usually feuding generic and brand name producers.

The resultant effect has been the issuance of only one compulsory license[298]- and not a single voluntary license- since 2004 when the law came into effect. In taking up increased participation in the scheme of things, the Government of Canada, through Health Canada, must set out in definite terms the extent it is ready to go in championing its humanitarian cause. It should be borne in mind that a pharmaceutical company, be it brand name or generics, has a commercial interest to protect. Therefore, placing reliance on pharmaceutical companies to implement a

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[298] One was issued to Apotex Group in September 2007. See Apotex Group, *Life Saving AIDS Drug for Africa gets Final Clearance*. Press Release of 30 September, 2007. Available at <http://www.apotex.com/PressReleases/20070920-01.asp>

purely humanitarian concept is preposterous and can only lead to the present situation of CAMR.

On-going efforts at amending the JCPA must not only aim at rectifying the disconnections in the JCPA discussed in Part IV but also to devise more than a passive role for the Government in its access to medicines drive. Models have been suggested in line with the above. One of the models outlines a system by which Canada could buy a needed pharmaceutical product from the patent holder, at a discount, and distribute freely in the eligible importing country using the health facilities of that country.[299]

The problems with this model are quite apparent in its conception. First, it entirely places the burden of meeting the health obligations of the importing country on the shoulders of another country. This is not a financial burden Canada, or any other rich country for that matter, can easily shoulder. Second, it is not probable that brand name companies will willingly sell pharmaceutical products, at lower prices, for Canada to merely actualize its humanitarian goal. The pharmaceutical companies would, if at all, rather undertake that as part of their corporate social responsibility and get the credit for it.

In an access to medicines context, the principal stakeholders must play active roles. By principal stakeholders I refer to the governments of the disease ravaged nations. Thus, I argue that a fundamental rule when deliberating on strategies to meet the access to medicines goal ought to be creating fiscal roles for the governments of the socially disadvantage people. The absence of an active participation by all those

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[299] Faina Weitsman, *The Trade- Related Aspects of Intellectual Property Rights (TRIPS) Agreement and Access to Patented Medicines in Developing Countries- Canada's Bill C-9* (LLM Thesis, University of Manitoba, 2006) [Unpublished].

who will be most affected by a lack of access to medicines is another reason past and present efforts have been failures. Governments of developing countries have shown a nonchalant attitude towards committing more financial resources to providing modern health care facilities for their people since they expect developed countries to shoulder this responsibility in their usually 'humane' manner.[300]

In light of the above, I suggest that the best model is one that imposes a corresponding, if not greater, responsibility on the developing country as it does a willing developed nation. My assertion and suggested model, the latter which I outline below, are premised on two facts: one, the initial state denial of the presence and destructiveness of AIDS in South Africa where the President Thabo Mbeki- led government refused to acknowledge the disease despite millions of South Africans suffering from it.[301] Two, the unwillingness of some African governments to maintain existing and or invest in new social and health infrastructures despite experiencing appreciable economic growth in the last decade.[302]

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[300] As at 2003, rich countries such as Denmark, The Netherlands, Luxembourg, Norway and Sweden have reached the target of making available 0.7 per cent of their Gross National Income (GNI) for Official Development Assistance (ODA) to developing countries, as recommended by the Pearson Commission in 1970. Finland, Spain, Belgium, UK and France had, in 2005, announced timetables to to reach the target. See Commission for Africa, *Our Common Interest: An Argument* (London: Penguin Books, 2005) p. 153. In Africa, however, only one country has met the African Union target of earmarking 15 per cent of their national budgets for health, as at 2003. See African Union, *Universal Access to HIV/AIDS, Tuberculosis and Malaria Services by A United Africa by 2010* - Special Summit of African Union on HIV/AIDS, Tuberculosis and Malaria (ATM) Abuja, Nigeria, 2-4 May 2006. Sp/Assembly ATM/2 (1) Rev.3. Online: AU, <http://www.africa-union.org/root/au/conferences/past/2006/may/summit/doc/en/ABUJA_CALL.pdf>

[301] Mandisa Mbali, "HIV/AIDS Policy- Making in Post-apartheid South Africa" in John Daniel, Adam Habib & Roger Southall, eds., *State of the Nation: South Africa 2003-2004* (Cape Town: HSRC Press, 2003) p. 312.

[302] In a recent article, a World Bank analyst estimated that about half of the countries in sub-Saharan Africa have witnessed an economic growth rate of about 4 per cent per year or more but without a corresponding impact on infrastructural development. See Benno Ndulu, *Infrastructure, Regional Integration and Growth in Sub-Saharan Africa: Dealing with the Disadvantages of Geography and Sovereign Fragmentation* (2006) 15:2 J. African Economies 212-244.

President Mbeki's skeptic stance on HIV/AIDS, evident in his statement: 'it seemed to me that we could not blame everything on a single virus'[303], obviously diminished the significance of the efforts of civil society groups, like the Treatment Action Campaign (TAC), and international AIDS organisations to stem the tide of the disease both in South Africa and in other countries in sub-Saharan Africa. Although the South African Department of Health went ahead to develop the "HIV/AIDS/STD Strategic Plan for South Africa: 2000-2005", the lack of political support from the government may have affected its implementation.[304]

On the other hand, one can argue that the acute shortage of health infrastructures and human resources, like health centers and qualified medical practitioners, and modern medical equipments have greatly contributed to the poor state of health of many people in developing countries. In addition, some developing states demand payment of patient's fees, as in Uganda, or primary healthcare fees, as in Tanzania, before poor sick people are treated for the most basic of illnesses.[305] As a result, access to essential medical assistance, where available, is prized out of the reach of the desperately sick.

To proffer a solution to this problem, experts drawn from African, European and North American countries, under the aegis of the Commission for Africa led by Tony Blair (while still the sitting Prime Minister of Britain), have canvassed an

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[303] Thabo Mbeki, *Speech of the President of South Africa at the Opening Session of the 13th International AIDS Conference, Durban, South Africa*. Office of the Presidency, 9 July 2000. Online: <http://virusmyth.net/aids/news/durbspmbeki.htm>

[304] Department of Health, *HIV/AIDS/STD Strategic Plan for South Africa: 2000-2005*. Online: DoH, <http://www.info.gov.za/otherdocs/2000/aidsplan2000.pdf>

[305] Commission for Africa, *Our Common Interest: An Argument* (London: Penguin Books, 2005) p. 68.

increase in aid from rich countries.[306] The Commission on Africa would appear to largely blame donor countries for the state of things in Africa as it contends that:

> Where aid is ineffective, donors are sometimes to blame as much as recipients. Donor countries must change their approach. They should all work to a single agreement, to be drawn up by the government in each African country. They should pay for what they have promised. And they should pledge aid over a long time-frame to allow African governments to plan better.[307]

Certain issues arise from this perspective. One, the provision of social amenities like healthcare centers, clean drinking water, access to medicines, etc., in Africa is hinged squarely on financial aid from rich donor countries.[308] And their lack is too quickly blamed on donor nations. The danger in this reasoning is that African governments have shown a propensity to shirk state responsibilities such as the provision and maintenance of functional hospitals, motorable roads, safe drinking water etc., since it is their expectation that rich western countries would take up the obligation to provide these basic infrastructures. Second, this initiative of the Commission on Africa presupposes that the problems of many African countries would be easily solved by throwing billions of dollars in financial aid at them.[309]

It is one's understanding that while many experts have not given thoughts to an equal or even lower financial commitment from African governments let alone seek to verify the uses to which previous financial aids have been put, the comity of donors appears not interested in pursuing accountability from developing nations for the funds already advanced to them. Moreover, it is presently the case that whereas

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[306] *Ibid.*
[307] *Ibid*, p.67.
[308] The Commission on Africa expects donors to support health systems in Africa with an additional US$10 billion a year by 2010, rising to US$20 billion a year by 2015. *Ibid,* p. 66.
[309] *Ibid.*

donors provide substantial financial aids to promote poverty reducing measures in developing countries, governments of those countries channel substantial resources to military expenditures.[310] The outcomes are the dismal budgetary allocations for healthcare[311] and the gasping lack of medical care for the sick in many Africa countries that in effect reflect the dangers in the Commission for Africa's approach.

5.4 Suggested Access Model

Using the flexible provision in paragraph 3 of the *Annex to the Protocol Amending the TRIPs Agreement* (with respect to members of regional trade agreement)[312], developing countries suffering similar public health problems could contribute an equal sum of money (out of their budgetary allocation for health) to a public health fund. The proceed of this fund can then be used to purchase an equally divisible essential drug necessary to treat a particular ailment, from a developed country whose Patent law permits bulk purchase of drugs by a group of countries.

The role of the developed country in this scheme will be to facilitate the issuance of a compulsory license to enable the production and export of the pharmaceutical product by a generic company to the group of countries. Realizing

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[310] Paul Collier & Anke Hoeffler, *Unintended Consequences: Does Aid Promote Arms Races?* (2007) 69:1 Oxford Bulletin of Economics & Statistics, pp. 1-27.

[311] Average spending on health per person in Africa in 2001 was between US$13 and US$21; in the developed world, it was more than US$2,000 per person per year. *Supra* note 305.

[312] "With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating local production of, pharmaceutical products: where a developing or least developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical produced or imported under a compulsory license in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question.

that the JCPA does not allow the grant of a single license to meet the medicines request of a group of countries, the JCPA could then be amended to accommodate this system.

The merits of this model outweigh the disadvantages. First, countries experiencing similar health problems will be enriched by and benefit from jointly tackling a common problem. Two, since the TRIPs Amendment already permits WTO members of regional trade agreement to engage in legitimate parallel importation of goods, developed countries should have no issues with accommodating the system in their domestic legislation. Three, pharmaceutical companies in the willing developed country will have more incentives to produce and export to the group of countries knowing that there is a larger market backed by the funds to pay for the product.

This model cannot in any way be foolproof. One challenge will be that developing countries do not all experience the same level of disease prevalence and so may not be ready to contribute equal amount to a common fund. Again, this model has not addressed the typical rancour between generic and brand name producers. It is supposed that domestic Patent laws of developed countries will fashion out a better means of interaction between licensees and patentees.

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